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LABORATORY SAFETY

AT THE

CENTER FOR DISEASE CONTROL

TWO SECTIONS

**SECTION I
ADMINISTRATIVE
ASPECTS OF
BIOSECURITY**

**SECTION II
PREVENTIVE ASPECTS
OF BIOSECURITY
FOR PERSONS WORKING
WITH HAZARDOUS
MICROBIOLOGIC AGENTS**

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**U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA 30333**

SECTION I

PREFACE
This section was prepared by the staff of
the Center for Disease Control
Atlanta, Georgia

**ADMINISTRATIVE
ASPECTS OF
BIOSECURITY**

LIBRARY
CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA 30333

TABLE OF CONTENTS

Section I

Preface	1
Introduction	2
Administrative Responsibilities	1
Office of Biosafety	1
Safety Officer	1
Archives Control Office	2
CDC Safety Committees	2
Postgraduate Training	2
Preventive Medical Services	3
Reporting	3
Restricted Areas	3
Signs Denoting Restricted Areas	4
Standards for Handling Nonhuman Primates	5
Use of Hand Washing Signs	7
Standards for Handling Contaminated Materials	37
Control of Light, Heat, and Humidity	35
Laboratory Exposure to Dangerous Microbial or Infectious Agents	37
Control of Air Flow in Laboratory Areas	41
Use of Laminar Air Flow Equipment	42
Accident Reporting	44
Laboratory Accident Investigation Board	46
Storage of Pathologic Specimens in CDC Laboratories and Related Materials	46
Exposure to Tetracycline Agents in Laboratories	48
Use of Hazardous Biological Agents	61
Electrical Safety	65
Use of Vacuum Equipment	74
Mouth Pipetting	74
Confined Spaces - Inspection and Entry	76
Lockout Methods	82
Distribution of Codes of Microbial Agents and of Vectors	86
Chemical Safety	88
Procurement, Management, and Disposition of Controlled Drugs	92
Ethyl Alcohol: Procurement, Usage, and Storage	100

PREFACE

This section was prepared by the staff of the Office of Biosafety, Center for Disease Control.

Selected Policy Statements and Forms

Labeling of Equipment Safety Maintenance/Repairs	101
Storage of Equipment, Supplies, and Materials in	
Corridor and Elevator Landings, CDC Facilities	107
NO SMOKING in Animal Quarters	111
Use of Chemicals: Fume Hoods During Non-Duty Hours	111
Corridors	111
Visitors in Laboratory Areas	117
Eye Wash Bottles	119
Caustic Chemicals and Eye Protection	121
Chemical Hazards	123
Disposal of Infectious or Toxic Laboratory Waste	125
Eye Protection	127
Decontamination	129
Regulatory Sink Drain to Surface Waste	129

TABLE OF CONTENTS

Section I

Preface	v
Introduction	ix
Administrative Responsibility	1
Office of Biosafety	1
Safety Office	1
Biohazards Control Office	2
CDC Safety Committees	2
Protective Clothing	2
Preventive Medical Services	3
Reporting	3
Restricted Areas	3
Signs Denoting Restricted Areas	4
Standards for Handling Nonhuman Primates	5
CDC Hazard Warning Signs	7
Standards for Handling Compressed Gases in Cylinders	29
Ultraviolet Lights – Use and Maintenance	35
Laboratory Exposure to Dangerous Chemicals or Infectious Agents	37
Control of Air Flow in Laboratory Areas	41
Use of Laminar Air Flow Equipment	42
Accident Reporting	44
Laboratory Accident Investigation Board	46
Storage of Flammable Solvents in CDC Laboratories (and Related Materials)	48
Exposure to Teratogenic Agents in Laboratories	58
Use of Hazardous Biological Agents	61
Electrical Safety	65
Use of Vacuum Equipment	74
Mouth Pipetting	75
Confined Spaces – Inspection and Entry	76
Lockout Methods	82
Distribution of Cultures of Microbial Agents and of Vectors	86
Centrifuge Safety	88
Procurement, Management, and Disposition of Controlled Drugs	93
Ethyl Alcohol: Procurement, Usage, and Storage	104

Selected Policy Statements and Forms

Labeling of Equipment Sent for Maintenance/Repairs	107
Storage of Equipment, Supplies, and Materials in Corridor and Elevator Lobbies, CDC Facilities	109
NO SMOKING in Animal Quarters	111
Use of Chemical Fume Hoods During Non-Duty Hours	113
Cannulas	115
Visitors in Laboratory Areas	117
Eye Wash Bottles	119
Caustic Chemicals and Eye Protection	121
Chemical Hazards	123
Disposal of Infectious or Toxic Laboratory Wastes	125
Eye Protection	127
Decontamination of Laboratory Sink Drains to Remove Azide Salts	133

ADMINISTRATIVE RESPONSIBILITY

The success of a safety program depends upon the participants' having the necessary knowledge to carry out the program. An employee who is aware of risks is less likely to be injured. The same is true if he or she has been trained in safe laboratory procedures, good biological techniques, and appropriate laboratory surveillance. Everyone who works in a laboratory should have such knowledge. Each must know how to protect those with whom he comes in contact. He should also know how to deal with laboratory emergencies -- either exposure of an individual to a dangerous agent or contamination of the physical environment. The likelihood of severe injury or infection is reduced if plans for such emergencies are established and well known to those who need to know them.

OFFICE OF BIO

INTRODUCTION

"Biosecurity" designates a broad program of preventive medicine designed to protect the health of employees who may encounter biological or chemical hazards in the laboratory or field. This manual brings together information that will assist supervisors in carrying out their responsibilities in biosecurity. Pertinent Center for Disease Control (CDC) policy is presented; offices that are available to assist supervisors in biosecurity are described; some specific responsibilities are discussed; and forms for reporting accidents and obtaining emergency medical care are shown.

The Office oversees all CDC safety activities at headquarters and field stations by developing and supervising implementation of safety policy. Policy is determined by the needs of CDC organizations, based upon experience gained from work situations; consultations with employees, safety experts outside of the CDC, and internal safety committees; and specific directions promulgated by higher headquarters and the Department of Labor (OSHA). This office also supervises control and use of narcotics and other products regulated by the Bureau of Narcotics and Dangerous Drugs.

The Office of Biosafety includes the Safety Office and the Biobehavioral Control Office.

SAFETY OFFICE

The Safety Office is primarily concerned with accident prevention and the health safeguards usually described as "Industrial Health." The Office emphasizes control of environmental factors.

Services include the monitoring of air for directional flow, velocity, and volume as well as for contaminants, such as chemicals, dust, noise, and the more common gaseous contaminants, that is, sulfur dioxide, carbon monoxide, mercury, ammonia, and chlorine. National standards of permissible tolerances for such items are kept on file for ready comparison and reference.

The Safety Office conducts a fire prevention and protection program. As part of this program, the Office inspects all emergency equipment, such as detection systems, alarm bells, and fire pumps. It conducts periodic fire drills. It places, inspects, and recharges fire extinguishers, evaluates fire hazards, and recommends protective measures.

Another function of the Office is to recommend special protective equipment and, if necessary, to provide it. This equipment includes safety glasses or goggles, safety shoes, and other protective apparel.

Editor's Note: Most of the material in this manual has been updated to reflect organizational changes.

ADMINISTRATIVE RESPONSIBILITY

The success of a safety program depends upon the participants' having the necessary knowledge to carry out the program. An employee who is aware of risks is less likely to be injured. The same is true if he or she has been trained in safe laboratory procedures, good biological techniques, and appropriate laboratory surveillance. Everyone who works in a laboratory should have such knowledge. Each must know how to protect those with whom he comes in contact. He should also know how to deal with laboratory emergencies — either exposure of an individual to a dangerous agent or contamination of the physical environment. The likelihood of severe injury or infection is reduced if plans for such emergencies are established and well known to those who need to know them.

OFFICE OF BIOSAFETY

The responsibility for enforcing and regulating the laboratory safety program ultimately rests in the Office of the Center Director. Immediate responsibility is with the employees themselves, their supervisors, and organizational units.

The Office of Biosafety supports the Center Director in all matters relating to safety and assists laboratory personnel and others in identifying and managing hazards. The biosecurity program conducted by this office is not punitive. It is preventive, protective, and educational.

The Office oversees all CDC safety activities at headquarters and field stations by developing and supervising implementation of safety policy. Policy is determined by the needs of CDC organizations, based upon experience gained from work situations; consultations with employees, safety experts outside of the CDC, and internal safety committees; and specific directions promulgated by higher headquarters and the Department of Labor (OSHA). This office also supervises control and use of narcotics and other products regulated by the Bureau of Narcotics and Dangerous Drugs.

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Another function of the Office is to recommend special protective equipment and, if necessary, to provide it. This equipment includes safety glasses or goggles, safety shoes, and other protective apparel.

The Office also measures light levels in work areas to determine if they are adequate and safe. It pays particular attention to ultraviolet light levels in laboratories and animal holding areas.

It supervises the safe disposal of chemical wastes and coordinates Civil Defense activities.

The CDC Radiation Safety Officer is located in the Safety Office and serves as a resource to all CDC installations using radioactive materials or equipment capable of producing ionizing radiation. In addition, he monitors use of and supervises disposal of radioactive materials at the headquarters facilities.

The Safety Office receives both personal and motor vehicle accident reports, investigates accidents, and prepares necessary reports for management. Claims for and against the government arising from official activities are also handled in the Office.

The Office conducts training in safety as part of the CDC in-house development program. It cooperates with various CDC efforts to incorporate safety training into regular training programs.

Occupational Safety and Health Act requirements for safety in the workplace are noted and brought to the attention of the Director, Office of Biosafety, for interpretation and implementation.

BIOHAZARDS CONTROL OFFICE

The Biohazards Control Officer works closely with the Safety Officer to provide special competency in the containment of infectious material and the management of chemical hazards. He gives technical guidance to the staff of the Center's laboratories and to all supervisors on the control and containment of etiologic agents, chemicals, and other hazards. Protecting laboratory workers, other Center employees, and the surrounding communities from hazardous agents has the highest priority. The Biohazards Control Officer develops methods to prevent cross-contamination, assure the sterility of equipment, and evaluate the safety of technical procedures.

The Officer coordinates the immunization of persons at risk. Another important part of his work is providing information about technical activities at the Center to the Center's nontechnical staff.

CDC SAFETY COMMITTEES

All CDC facilities, depending on their size, have either safety committees or designated senior officials who serve as safety officers. The safety committees in the field installations are conventional in that they are composed of management-level officials. The headquarters' committee is different in that all members are volunteers who have indicated a strong interest in safety matters and have direct and immediate access to top management through the committee chairman, a senior official on the Director's staff. The CDC Safety Officer and Biohazards Control Officer are ex officio members of the committee and participate in all meetings. Membership is rotated annually to give interested employees an opportunity to participate and to contribute.

PROTECTIVE CLOTHING

The Center provides some categories of personnel with surgical caps and masks and complete changes of laboratory clothing, including shirts, trousers, shoes, coats, and smocks. This clothing helps protect against agents present in the work areas. Because these garments are associated with work hazards, especially infectious agents, wearing them away from Center facilities — such as to and from work or to the bank during the lunch period — is prohibited. Using laboratory coats as all-purpose wrappers in areas used by visitors and the nonlaboratory staff, such as the cafeteria, library, and administrative offices, is unnecessary and causes concern that the coat may have been exposed to hazards in the work area. Such use is not authorized.

PREVENTIVE MEDICAL SERVICES

The Center's health policy for employees is based on good preventive medical practice and the specific needs of persons working in areas of increased risk. The activities which make up the CDC program of preventive medicine fall into three general categories: (1) general requirements, (2) special requirements, and (3) emergency and voluntary health services.

(1) General Requirements

Medical examinations of new employees selectively include a medical history, physical examination (includes Pap smear for females), skin test for tuberculosis, serology plus a serum specimen for the CDC serum bank, selected biochemical tests, a complete blood count, urinalysis, needed immunizations, an X-ray, an electrocardiogram (EKG) as indicated, and an audiometric examination.

This data provides a basis for comparison in the event a job-related disease occurs and encourages good preventive medical practice.

(2) Special Requirements

Special examinations and immunizations are required for some positions as a *condition of employment*. Work in some areas may involve possible exposure to hazardous microbiological agents and thus may require prior immunization. Since requirements for persons at special risks vary, the Center Director establishes these requirements. Recommendations for special immunizations appear in Section II, "Preventive Aspects of Biosecurity for Persons Working with Hazardous Microbiologic Agents." Whenever possible, evidence of antibody response should be demonstrated before an employee begins to work with infectious agents. The employee's supervisor is responsible for implementing the requirements.

(3) Emergency and Voluntary Health Services

The USPHS Outpatient Clinic at CDC provides emergency medical care for all CDC employees in the Atlanta area. In addition, many voluntary health services are provided, such as the Federal Employee Health Program in which biennial examinations are offered to all employees over 40 years of age. From time to time, immunization campaigns, tuberculosis screening programs for employees and their families, blood typing and donation services, and other special health activities are offered. Emergency medical care is available from a variety of sources for employees located outside the Atlanta area. Supervisors must be familiar with the source of emergency medical care for their personnel and with the procedures for obtaining it.

REPORTING

The prompt and proper reporting of hazards and accidents is essential to an effective biosecurity program. In general, when a problem arises, the employee must notify his supervisor immediately. The supervisor determines whether to request assistance from the CDC, Office of Biosafety. Written reports must follow. Details on making reports are described in the manual guides, policy statements, and forms included in Section I of this manual.

RESTRICTED AREAS

Biological and chemical laboratories and all other potentially hazardous areas are off bounds to anyone who is not assigned to that area and who does not need to be there. A laboratory cannot be completely isolated, however, and a reasonable amount of personnel movement is essential. At CDC, certain areas are designated "restricted areas." Door and wall signs and other markers indicate the degree of restriction.

Persons are authorized to enter laboratories if they are properly immunized, understand inherent risks, and need to be in the areas. Official visitors, including students, are authorized to enter the Center's restricted laboratory areas on the same basis; their safety, however, is a responsibility of the laboratory supervisor. The supervisor determines if a given person may enter a restricted area, and he sees that the visitor receives appropriate instruction. Visitors who do not meet the requirements for entry are met in unrestricted parts of the Center.

SIGNS DENOTING RESTRICTED AREAS

The degree to which access to CDC facilities is limited depends upon the risk associated with being in an area — the greater the hazard, the more stringent the entrance requirements.

Corridors are the least hazardous of any locations in restricted laboratory areas.

Areas in which the work is associated with greater degree of risk are marked by signs reading "Caution, do not enter without permission of (name of investigator)" or "Caution, do not enter without current immunization against (name of disease)". These signs are posted only while risk is present. The location of the areas varies with the work.

Access to infected animal holding areas may require certain immunizations and permission from the Chief of the Research Animal Unit. Access to the Animal Breeding and Holding Facility is by invitation of the Chief of the Unit. The purpose of this restriction is to protect the breeding stock against infections introduced by man. Access to some areas is restricted to the staff assigned to them. Visitors may see these facilities only when the areas have been completely decontaminated and no work is under way.

No-access areas are marked with signs reading "Warning, highly infectious material — Keep Out". In temporary situations, such as following an accident, a large sign with "Danger, DO NOT ENTER, Contaminated Areas," printed in bright red, is posted. Areas posted with either of these signs are off limits to *all* personnel except the investigator who posted the sign. One should not pass these signs for *any* reason, not even to fight fire. These signs are seldom used. The exception is that the "Warning — highly infectious material — Keep Out" sign is permanently posted on a few deep freezers used to store very dangerous agents.

In the Atlanta area, questions about the location of restricted areas, the hazards and the risks of infection in the areas, times when restricted areas can be visited, and immunizations should be directed to the Biohazards Control Officer: telephone 633-3311, extension 3883. At field stations, information regarding restricted areas is available from the Chief of the station.

STANDARDS FOR HANDLING NONHUMAN PRIMATES

Section I. Introduction

II. Standards

I. INTRODUCTION

Nonhuman primates are dangerous to handle. They not only may injure personnel who are working with them but they may also carry serious diseases which can be contracted by man (e.g., shigellosis, hepatitis, tuberculosis, monkey B virus, green monkey disease, and others). Infectious agents can be spread by many routes - through air, from objects soiled with excreta, and from scratches and bites.

The standards prescribed in this Guide are designed to reduce the risk from working with nonhuman primates. Supervisors are responsible for ensuring that employees under their supervision who work with these animals are aware of and comply with these standards.

II. STANDARDS

A. This Guide sets forth minimum standards for CDC employees who work with nonhuman primates or nonhuman primate tissues. Each division or program which has employees working with nonhuman primates is expected to develop specific safety procedures designed for its particular situation to supplement these standards. In any case where there is need for exceptions to the standards in this Guide, a written request describing the circumstances and alternate procedure should be sent to the Office of Biosafety for action.

B. Minimum standards for working with nonhuman primates or nonhuman primate tissues are as follows:

1. Only experienced animal handlers are qualified to and will transfer, restrain, or handle nonhuman primates. The animal handlers will wear heavy gloves and longsleeved protective clothing. Under no circumstances will anyone place bare hands in a cage containing the nonhuman primates.

(II continued)

2. Laboratory technicians, animal handlers, and all others will wear face masks and protective clothing while working with the nonhuman primates. Each holding area will provide the necessary masks and operating gowns or equivalent protective clothing. Due to the high rate of intestinal infections of nonhuman primates with pathogens also common to man, it is important that all employees thoroughly wash their hands and forearms after working with these animals.
3. Animal handlers who are initially negative to the tuberculin test should be retested every six months until they become positive to the skin test and, thereafter, should have a chest X-ray once each year.
4. When employees are scratched or bitten by a nonhuman primate, the wounds (even superficial ones) must be scrubbed for three minutes with soap and water, then thoroughly rinsed with warm water, dried with clean absorbent cotton or a surgical sponge, and swabbed with a 1% solution of Zephiran chloride. These injuries should be promptly reported to the employees' supervisors who will immediately arrange for medical care at the Outpatient Clinic at the Clifton Road facility or at another appropriate medical authority.
5. Necropsies on nonhuman primates should be performed only by professionally trained employees who are protected by gloves, masks, and gowns. These necropsies should be done only in a special area designed for the containment of potentially virulent and communicable micro-organisms. The necropsy area and all instruments and equipment should be thoroughly cleaned and decontaminated after each use.
6. Nonhuman primates that cannot be necropsied under the recommended conditions in "5." above should be carefully placed in plastic bags to prevent contamination of the exterior of the bag and then should be incinerated.
7. All nonhuman primate tissues and fluids, particularly tissue cultures prepared from organs of nonhuman primates, should be handled as if infected with agents transmissible to man.
8. Employees who work with nonhuman primates or their tissues and who have a fever or have other symptoms that may be associated with infections must promptly notify their supervisors who will immediately arrange for medical care at the Outpatient Clinic at the Clifton Road facility or at another appropriate medical authority. Regardless of the reason for visiting the Clinic or other medical authority, these employees must always tell the physician or nurse that they work with nonhuman primates. It is equally important that physicians caring for CDC employees be aware that exposure to nonhuman primates or other unusual sources of infection may have occurred and that patients be questioned to establish these relationships.

CDC HAZARD WARNING SIGNS

- Section I. Purpose
II. Description
III. Policy
IV. Method of Posting
V. Availability of Signs and Frames

I. PURPOSE

In an effort to bring uniformity to the system of signs used in the Center for Disease Control to warn of danger and to direct "pedestrian traffic" away from laboratory work areas, a new group of hazard warning signs has been designed. This Guide describes the signs and sets forth the conditions under which the signs are to be posted. It is important that all CDC employees and visitors comply with the policy for entering areas where these signs have been posted.

II. DESCRIPTION

CDC hazard warning signs are illustrated in Exhibits 1-9. The signs inform CDC personnel and visitors that a hazard exists in an area. The degree of danger is indicated by the sign. In high risk areas, admission is forbidden to all except those assigned to that area; in lower risk areas, visitors must secure permission to enter from the investigator in charge of the work. Other signs warn that one must have special immunization before entering the area.

III. POLICY

Exhibits 1-9 specify the conditions under which the hazard warning signs will be posted. The investigator in charge of the laboratory is responsible for posting the signs in accordance with policy set forth in this Guide. Upon request, the CDC Office of Biosafety will assist investigators in determining the need for posting warning signs.

The signs will be posted only while a hazard exists and must be taken down as soon as the source of danger is removed. Hazard signs will not be posted when no hazard exists, i.e., to discourage traffic through an area.

At the end of working hours, laboratory work areas should be decontaminated so that janitors, plant engineers, firemen, and other can safely enter the areas. If this is not done, a special "DANGER - DO NOT ENTER" sign (Exhibit 9) must be posted.

Hazard warning signs will show the names of the hazard(s) and the investigator and his alternate and their home telephone numbers. When appropriate, similar signs will be posted on both the laboratory and animal holding rooms.

The investigator named on the hazard sign will determine when visitors can be allowed in the laboratory. He is responsible for their safety while they are there. Visits are restricted to those who have a need to observe laboratory procedures. Social visits by CDC staff and visitors are prohibited while a biohazard exists.

IV. METHOD OF POSTING

Signs that are to be used permanently will be posted only in permanent frames. At headquarters, the frames will be installed only by Engineering Services Branch. (Requests for installation will be submitted to Engineering Services Branch on Form PHS 0.362 (CDC). The form is available from the CDC Warehouse and the Self-Service Store at the Clifton Road Facility.) At installations outside the headquarters area, the frames will be installed on a uniform basis by a qualified maintenance employee. The investigator in charge of the laboratory is responsible for requesting the installation of the frames.

Signs that are to be used on a temporary basis (less than one month) will be posted in permanent frames if they have been installed. If frames have not been installed, these signs will be posted with masking tape on a glass surface or, if more appropriate, on refrigerators, freezers, doors, etc.

Signs will not be posted with tacks, pins, and various adhesive materials that will damage the doors, walls, or building when the signs are removed.

V. AVAILABILITY OF SIGNS AND FRAMES

The Safety Office will maintain the supply of the CDC hazard warning signs and frames. Plastic fronts will be available for signs to be posted on outside doors.

The investigator in charge of the laboratory is responsible for securing the appropriate signs and frames. He should submit a memorandum of request to the CDC, Office of Biosafety.



Capacities:	
<input type="checkbox"/>	Caustic
<input type="checkbox"/>	Corrosive
<input type="checkbox"/>	Explosive
<input type="checkbox"/>	Flammable
<input type="checkbox"/>	Toxic
Chemicals	

CAUTION**CHEMICAL HAZARD**

The sign illustrated in Exhibit 1b will be posted when an unusual chemical hazard exists.

Gum-backed stickers are available from the NCDC Safety Office for adding to the signs the following information:

Danger - Acid

Danger - Caustic

Danger - No Smoking

Danger - Poison

Danger - Corrosive Liquids-Use Personal Protective Equipment

Danger - Flammable-Keep Flames and Heat Away

The sign informs that a hazard exists and that visitors to the laboratory should take appropriate caution.

V. AVAILABILITY OF SIGNS AND FRAMES

The Safety Office will maintain the supply of the CDC hazard warning signs and frames. Plastic frames will be available for signs to be posted on outside doors.

CAUTION



CHEMICAL HAZARD

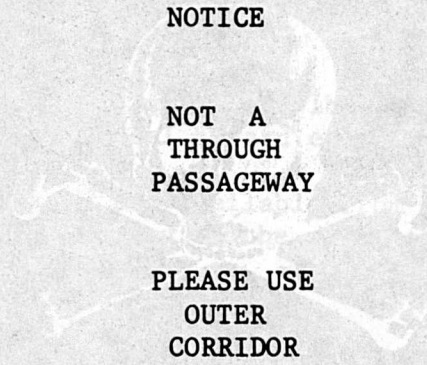
Contains:

- ☐ Caustic
- ☐ Corrosive
- ☐ Explosive
- ☐ Flammable
- ☐ Toxic

Chemicals

CDC - SAFETY OFFICE

CAUTION

NOTICE

NOT A
THROUGH
PASSAGEWAY

PLEASE USE
OUTER
CORRIDOR

The sign illustrated in Exhibit 2b will be posted to discourage traffic through laboratory corridors.

Air supplies in laboratory corridors must be carefully balanced to assure that any infectious material released in the laboratories is swept into the exhaust air ducts and not back into the corridors. Opening the doors at the ends of the corridors upsets this air balance.

Only persons going to a laboratory on the floor should use the laboratory corridor.

Contains:

Carcinogenic	<input type="checkbox"/>
Corrosive	<input type="checkbox"/>
Explosive	<input type="checkbox"/>
Flammable	<input type="checkbox"/>
Toxic	<input type="checkbox"/>

Chemicals

CDC TN-69.1 4/22/69

CDC TN-69.1 4/22/69

NOTICE

**NOT A
THROUGH
PASSAGEWAY**

**PLEASE USE
OUTER
CORRIDOR**

CDC - SAFETY OFFICE

NOTICE

NO
PASSENGERSSERVICE
ELEVATORS

The sign illustrated in Exhibit 3b will be posted to keep service elevators free of passenger traffic.

Certain elevators were designed as supply routes to the laboratories from central service areas. Employees must use service elevators for moving media, glassware, and other equipment. Passenger elevators cannot be used for this purpose. Service elevators must be kept free of passenger traffic.

NOTICE

**NO
PASSENGERS**

**SERVICE
ELEVATORS**

CDC - SAFETY OFFICE

CAUTION

BIOLOGICAL
HAZARD

DO NOT ENTER
WITHOUT CURRENT
IMMUNIZATION
AGAINST:

The sign illustrated in Exhibit 4b will be posted on the doors of areas where infectious agents that require immunization of personnel are being used.

Every attempt will be made to limit the restriction to as small an area as possible and the sign will be posted only when a hazard requiring immunization exists.

It is important the non-immunized personnel or personnel whose immunization has expired not enter any area where this sign is posted. Violations of this regulation may result in exposure of susceptible persons to agents capable of causing serious disease and can be the basis for disciplinary action.

CAUTION



BIOLOGICAL HAZARD

DO NOT ENTER

Without Current Immunization Against:

CDC - SAFETY OFFICE

CAUTION

CAUTION

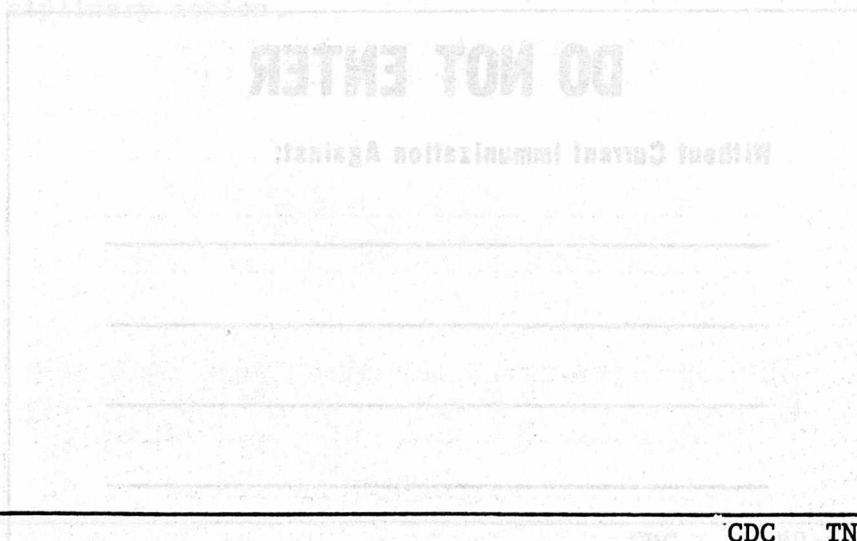
BIOLOGICAL HAZARD

INFECTIOUS AGENTS

The sign illustrated in Exhibit 5b will be posted on the doors of laboratories where work is being done with infectious agents that require special conditions for containment. The need for this warning sign will depend on the kind of study as well as the pathogenicity of the agent.

Laboratory supervisors are responsible for assessing the risk and the need for warning signs. The CDC Biological Hazards Officer is available to assist in making this determination.

Visits in these areas are prohibited unless the visitor has permission from the investigator in charge, who is responsible for the safety of the visitor while he is in the area.



CDC TN-69.1 4/22/69

CAUTION



BIOLOGICAL HAZARD


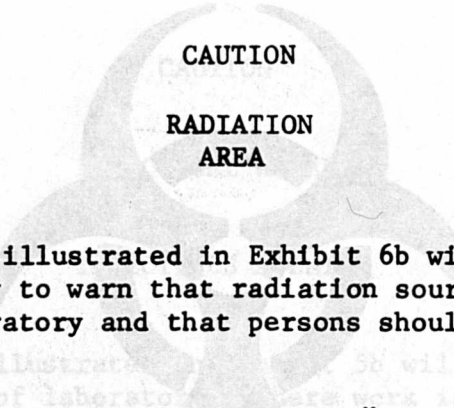
INFECTIOUS AGENTS

Do Not Enter Without Authorization From:

Day: _____ Night: _____

Day: _____ Night: _____

CDC - SAFETY OFFICE



CAUTIONRADIATION
AREA

The sign illustrated in Exhibit 6b will be posted when necessary to warn that radiation sources are present in the laboratory and that persons should, therefore, be cautious.

Additional information such as "DO NOT ENTER," "CONTACT DR. _____ for permission to enter," etc., may be added by the investigator.


INFECTIOUS AGENTS

CDC TN-69.1 4/22/69

CAUTION



RADIATION AREA

DO NOT ENTER
HIGHLY INFECTIOUS AGENTS

Source _____

In Emergency Call: _____

Day: _____ Night: _____

CDC - SAFETY OFFICE

CAUTION

BIOLOGICAL
HAZARDDO NOT ENTER
HIGHLY INFECTIOUS AGENTS

The sign illustrated in Exhibit 7b will be posted when freezers, refrigerators, rooms, or entire work areas where highly dangerous materials are kept or are being used. The sign will be removed when the hazard no longer exists.

Only persons who work in the laboratory may enter the area when this sign is posted.

Service personnel such as janitors, engineers, repair crews, firemen, etc., will not enter unless accompanied by the investigator in charge of the area. Fire, flooding, or mechanical failures in such an area will be left alone until investigators named on the sign are present to determine that the area can safely be entered.

Failure to observe this sign may result in exposure to extremely pathogenic agents and can result in disciplinary action.

CAUTION



BIOLOGICAL HAZARD

DO NOT ENTER HIGHLY INFECTIOUS AGENTS

In Case of Fire or Mechanical Failure

Call: _____

Day: _____ Night: _____

CDC - SAFETY OFFICE

CAUTION**BIOLOGICAL
HAZARD****INFECTED ANIMALS**

The sign illustrated in Exhibit 8b will be posted when animals that are "on test" may shed the infectious agent used in the study or when animals must not be exposed to any sources of infection (including visitors). The sign illustrated in Exhibit 7b also may be used to warn of infected animals.

Visitors to the animal quarters must be accompanied by personnel assigned to the area.

CAUTION



BIOLOGICAL HAZARD

INFECTED ANIMALS

Visitors and CDC Personnel not Assigned to this
Area Contact:

Ext: _____ Before Entering.

CDC - SAFETY OFFICE

DANGER

DO NOT
ENTER

CONTAMINATED AREA

The sign illustrated in Exhibit 9b will be posted only on a temporary basis when an extremely hazardous condition exists. It will not be posted on long-term hazardous areas (See Exhibit 7b - CAUTION - BIOLOGICAL HAZARD - DO NOT ENTER - HIGHLY INFECTIOUS AGENTS.)

Normally, each laboratory will be "secured" at the end of each work day. Infected materials will be stored in refrigerators, incubators, etc.; table tops will be wiped down with an appropriate disinfectant; contaminated glassware and equipment will be in covered disposal pans ready to go to the autoclave. The area will be safe for entry by the night cleaning crews and other service personnel; all hazard sources will have been contained for the night.

However, if it is not possible to "secure" the laboratory because of the work being done or if a spill has occurred and the laboratory (or other area) is contaminated and is not safe to enter, this sign will be taped on the door and left up until the hazard is removed.

No one except the investigator will enter while this sign is posted.

DANGER

DO NOT ENTER

CONTAMINATED AREA !

POSITIVELY NO ADMITTANCE
WITHOUT PERMISSION FROM PERSON LISTED BELOW

1	CDC	HOME
2	CDC	HOME
3	CDC	HOME

STANDARDS FOR HANDLING COMPRESSED GASES IN CYLINDERS

- Section
- I. Introduction
 - II. General Standards
 - III. Restricted Products
 - IV. Flammable Gases - Hydrogen, Acetylene, and Others of this Classification
 - V. Acceptance of Cylinders from Vendors
 - VI. Handling and Storage of Cylinders
 - VII. Pressure Regulators and Needle Valves
 - VIII. Leak Testing
 - IX. Empty Cylinders

I. INTRODUCTION

Users of compressed gases should be familiar with the pertinent equipment and the characteristics of the gases. The Office of Biosafety has information available on most of the gases likely to be used in CDC laboratories. It has detailed information available on detecting leaks, selecting needle valves and regulators, toxicity, explosion hazards, chemical incompatibilities, etc.

II. GENERAL STANDARDS

- A. Cylinders of compressed gas must be secured at all times so they cannot fall.
- B. Valve safety covers should be in place until pressure regulators or needle valves are ready to be attached.
- C. The contents of cylinders must be identified with decals, stencils, glued or wired-on tags, or other markings on the cylinders. Color codes alone or tags hung around the necks of the cylinders are not acceptable. Cylinders lacking proper identification must not be accepted from the vendors.
- D. Cylinders may be moved on hand trucks, carts, dollies, etc.; they must never be rolled or dragged.
- E. Employees must not attempt to repair cylinders or cylinder valves or to force stuck or frozen cylinder valves.

III. RESTRICTED PRODUCTS

- A. Highly toxic gases may be purchased and used only upon written permission of the Chief, Office of Biosafety. He must be notified of intent to work with highly toxic gases prior to their proposed purchase to allow time for taking necessary safety preparations. Large cylinders of toxic gases should not be purchased if it is possible to use small cylinders.
- B. Laboratories using toxic gases should have gas masks available that are effective against the agent. (The Office of Biosafety will loan masks with appropriate filters.) The supervisor is responsible for employees' instruction in how to use masks and other protective equipment. Purchase and use of the following gases are controlled:
1. Boron trifluoride
 2. Chlorine
 3. Chlorine trifluoride
 4. Dimethylamine
 5. Ethylene oxide (other than 12/88 sterilizing mixtures)
 6. Fluorine
 7. Hydrogen bromide (hydrobromic acid)
 8. Hydrogen chloride (hydrochloric acid)
 9. Hydrogen fluoride (hydrofluoric acid)
 10. Hydrogen sulfide
 11. Iodine pentafluoride (liquid shipped in gas-type cylinders)
 12. Methyl bromide (bromomethane)
 13. Methyl chloride
 14. Nitric oxide
 15. Nitrogen dioxide (nitrogen tetroxide)
 16. Nitrogen trioxide
 17. Nitrosyl chloride (nitrogen oxychloride)
 18. Phosgene
 19. Silicon tetrafluoride (tetrafluorosilane)
 20. Sulfur dioxide
- C. The Chief, Office of Biosafety, will notify investigators in charge of laboratories as soon as it is determined that the gas can be used safely. Some of these gases are extremely toxic and may require isolated laboratory space and equipment not immediately available. For this reason, clearance should be requested well in advance of the proposed use.

IV. FLAMMABLE GASES - HYDROGEN, ACETYLENE, AND OTHERS OF THIS CLASSIFICATION

Because of the fire and explosive hazards that can result when these products are used in confined spaces, special care must be used.

- A. When cylinders are kept inside the building, two or more cylinders should not be manifolded together. However, several instruments may be operated from one cylinder.
- B. If more than one cylinder of highly flammable gas is to be placed in a laboratory room, written permission must be obtained from the Chief, Office of Biosafety. Considerations for granting permission will include size of the room, airflow, other equipment in use (crowding), ease of access to cylinders, etc. Future changes and rearrangements will require permission of the Chief, Office of Biosafety.
- C. Standby cylinders of flammable gases (full reserve cylinders) or empty cylinders must not be stored in the laboratory. Cylinders will be stored out of doors and delivered to the laboratory on demand. (This does not change the responsibility of the user to initiate purchase orders.) Empty cylinders will be removed from the laboratory when the full cylinders are received.
- D. Cylinder size will be limited to 200 cubic feet.
- E. When practical, valves on flammable gas cylinders should be closed before all employees leave the laboratory at night.
- F. Adapters may be used only upon written permission of the Chief, Office of Biosafety (see Section VII).
- G. Piping must be compatible with the gas, e.g., no copper for acetylene, no plastic tubing in any high pressure portion of a system, etc.

V. ACCEPTANCE OF CYLINDERS FROM VENDORS

- A. The contents of cylinders must be identified with decals, stencils, glued or wired-on tags, or other markings on the cylinders. Color codes alone or tags hung around the necks of the cylinders must not be used. Cylinders lacking proper identification must not be accepted from the vendor.

V. ACCEPTANCE OF CYLINDERS FROM VENDORS (Continued)

- B. Cylinders must not be accepted from the vendors unless the valve safety covers are in place and properly tightened.
- C. Vendors moving cylinders in CDC buildings must use hand trucks, carts, or dollies. Cylinders must not be dragged or rolled.
- D. Cylinder valves must conform to standards of the National Compressed Gas Association.

VI. HANDLING AND STORAGE OF CYLINDERS

- A. Cylinders should never be dropped or permitted to strike each other violently.
- B. The valve safety covers must be left on the cylinders until they are secured to walls, benches, or stable pieces of equipment, or until nontip bases are attached.
- C. Cylinders must be transferred only by carts, hand trucks, or dollies. They must not be rolled or dragged. The valve safety covers must be in place and the cylinders secured to the carts during transport.
- D. Empty cylinders must be marked "EMPTY" or "MT" with grease pencils. Generally, this marking should be on a large piece of adhesive or masking tape stuck on the cylinder rather than on the tank itself. However, some cylinders have tags wired to the valve that identify their contents; in this case, the bottom half of this tag may be torn off to indicate an empty cylinder. In all cases, empty cylinders must be easily identified so as not to be confused or stored with full cylinders.

VII. PRESSURE REGULATORS AND NEEDLE VALVES

- A. The valve fittings of cylinders used to store different families of gases are different and will only allow regulators or needle valves to be attached that are safe for use with those gases. Cylinders must not be purchased or accepted whose fittings do not conform to standards of the National Compressed Gas Association. Use of adapters to connect regulators to cylinder valves defeats this safeguard and must not be used without written permission of the Chief, Office of Biosafety. Only pressure regulators and needle valves approved for the gases may be used.

VII. PRESSURE REGULATORS AND NEEDLE VALVES (Continued)

B. Threads and points of unions must be clean; these surfaces must be inspected before they are connected. Personnel must not attempt to lubricate threads or fittings.

C. When attaching regulators or needle valves, personnel must tighten the connections firmly. Nonadjustable wrenches of the proper size should be used. Pliers or adjustable wrenches should not be used, as they damage the nuts, most of which are brass and rather soft. Need for excessive force often indicates that the regulators or needle valves do not fit the cylinders. Leaks at the unions between the regulators and the cylinder valves are usually due to damage to the faces of the connections. Attempts to force a tight fit may damage the previously undamaged half of the connection. If the cylinder valve faces are damaged, the cylinders must be returned to the vendor. Employees must not attempt to repair them. Damaged regulators must not be used until repaired.

D. After attaching the pressure regulator to the cylinder, personnel should turn out the delivery pressure adjusting screws of the regulators until they turn freely. The cylinder valves should be opened slowly. Laboratory personnel should avoid standing directly in front of the regulators at this time as the pressure of the cylinders may blow the glass from the front of a faulty gauge.

The cylinder valve handles should be left attached to the valves while the cylinders are in use. Cylinder valves that "stick" and do not open when the usual amount of force is applied may be damaged. Personnel must not attempt to force them open, but should return these cylinders to the vendors, stating on the cylinders that the valves are stuck.

E. Pressure in full cylinders should be as indicated on the cylinders or labels. Lack of full pressure may indicate leaks at the connections between the cylinders and valve regulators, damaged regulators, or incompletely filled cylinders.

F. Employees should connect delivery lines to the low pressure outlets of the regulator valves or to the needle valves. Where low pressure lines are used, their valves should be closed and line pressure adjusted by turning the regulator delivery pressure adjusting screws until the desired pressures are shown on the delivery pressure gauges.

G. If the gases are not to be used over a considerable length of time (i.e., 24 hours), the cylinder valves should be closed, the lines bled, and the pressure adjusting screws turned back until they turn freely. Damage to the gauges may result if pressure is left on the gauges during extended periods of nonuse.

VIII. LEAK TESTING

A. Leak testing using "snoop" or a soap solution should be done twice. The first test should be made before the regulator or needle valve is attached to determine if there are leaks at the union of the cylinder and the cylinder valve and to determine if the valve is leaking. The second test should be made after the regulator is attached and the cylinder valve is opened to detect leaks around the valve stem packing, the connecting fittings, the regulator or needle valve, and the transfer lines to the instrument.

B. Compressed gas cylinders are tested for leaks when they are filled; however, leaks have been detected when cylinders were received in CDC laboratories. Personnel should not attempt to repair cylinder leaks or leaks caused by loose valve stem packings. Leaking cylinders of nontoxic, nonflammable gas may be taken to a loading dock or other place having suitable air flow for the vendors to pick up. Leaks from cylinders of toxic or flammable gases require immediate attention. Decisions of how to handle the problem will depend on the kind of gas, the size of the leak, the area where the cylinder is located, and other factors. Personnel must wear gas masks and appropriate protective clothing when attempting to move leaking cylinders of toxic gases.

Assistance can be obtained from the Office of Biosafety, local fire departments, or nearby military bases - depending on the location of the laboratory and the hazard.

IX. EMPTY CYLINDERS

A. A small amount of gas must be left in the cylinders and the cylinder valves must be closed to prevent contamination of the inside of the cylinders.

B. Empty cylinders should be marked "EMPTY" or "MT" and stored apart from full cylinders. (See Section VI. D.)

C. Valve safety covers and the labels showing contents must be in place.

D. Demurrage charges continue until cylinders are returned to the supplier; therefore, empty cylinders should be returned promptly.

ULTRAVIOLET LIGHTS - USE AND MAINTENANCE

Section I. Introduction

II. Guidelines

III. Radiation Exposure

I. INTRODUCTION

Ultraviolet radiation includes that portion of the radiant energy spectrum between visible light and X-rays (approximately 3900 to 136 angstrom units). Under certain conditions, including radiation intensity and exposure time, ultraviolet radiation will kill many kinds of microorganisms, its greatest effectiveness being against vegetative forms. Ultraviolet light is not a sterilizing agent, however, except in certain exceptional circumstances. Rather it is used to substantially reduce the number of microorganisms on surfaces and in the air.

II. GUIDELINES

Low pressure mercury vapor lamps which emit 95 percent of their radiation in the 2537 angstrom units region are generally used for germicidal purposes. These lamps are used in many locations in the CDC to reduce the numbers of pathogenic microorganisms on exposed surfaces and in the air. Since such factors as lamp age and dust accumulation contribute to decreased efficiency of these lamps and since care is required to maintain and use them properly and safely, the following guidelines have been developed:

- A. The CDC Safety Office is responsible for periodic intensity testing of all ultraviolet installations. Ultraviolet lamps will be replaced when they emit 70 percent or less of their rated initial output. This figure is higher than the manufacturer's suggested cutoff point. The safety factor thus provided permits semiannual testing and virtually eliminates the possibility of complete failure within a short time after passing a satisfactory intensity test.
- B. Ultraviolet lamps in air locks and door barriers will be turned on continuously. Skin or eye protection is not usually required for persons walking through these areas. Protection is required, however, for persons exposed to the radiation for longer than a few seconds.

Ultraviolet lamps in Biological Safety Cabinets (BSC) will be turned on only when the cabinet is not in use. (The lamps in the BSC lethal chamber above the filters are turned on automatically when the blower is turned on.)

Personnel must wear protective equipment (goggles, caps, gowns, and gloves) or turn off the lights before entering laboratories, animal rooms, etc., which have ultraviolet installations.

- C. All ultraviolet lamps except those located in the BSC lethal chamber (above the filters) must be cleaned at two-week intervals, or more often, if located in an unusually dusty area. The lamps should be turned off and wiped with a soft cloth pad moistened with alcohol. Cleaning is the responsibility of the personnel in charge of the laboratory. Cleaning dates should be noted on a card attached to the installation.
- D. Special problems concerning use, cleaning, or installation of ultraviolet lamps should be referred to the CDC Safety Officer or the CDC Biological Hazards Officer.

III. RADIATION EXPOSURE

The eyes and skin should not be exposed to direct or strongly reflected ultraviolet radiation. The effect of radiation overexposure is determined by such factors as dosage, wave length, portion of body exposed and the sensitivity of the individual.

Overexposure of the eyes will result in a painful inflammation of the conjunctiva, cornea, and iris. Symptoms will develop 3 to 12 hours following exposure. There is a very unpleasant foreign body sensation accompanied by lacrimation. The symptoms usually disappear in a day or two.

Exposure to the skin will produce erythema (reddening) 1 to 8 hours following exposure.

Adequate eye and skin protection must be worn when working in an irradiated area. Safety glasses with side shields or goggles with solid side pieces should be worn. The side pieces prevent the entrance of reflected radiation and direct radiation from a side source. Skin protection is afforded by face shields, caps, gloves, gowns, etc.

Overexposure to ultraviolet radiation should be reported in accordance with procedures in Personnel Guide for Supervisors, Chapter IV, CDC Guide 8-1.

LABORATORY EXPOSURE TO DANGEROUS CHEMICALS OR INFECTIOUS AGENTS

Section I. Introduction

- II. Dangerous Chemicals
- III. Routes of Infections
- IV. Policy
- V. Procedures Following Exposure or Accident

I. INTRODUCTION

Safety is an intrinsic part of each laboratory operation; work is planned so that exposure to hazardous agents will not occur. In spite of this, accidents that create hazards do occur. These often involve spills or area-wide contamination with dangerous chemicals or infectious agents. Likelihood of severe injury or infection can be reduced if plans for such emergencies are established and are well known to all who need to know.

II. DANGEROUS CHEMICALS

Dangerous chemicals may be of several types. Special care must be taken when large quantities of these materials must be handled or stored.

- A. Caustic or corrosive. Examples: Acids or bases which may burn or otherwise damage the skin and other human tissue. Consideration also must be given to corrosion of equipment.
- B. Poison. In this category are substances which are so poisonous that inhalation or ingestion of relatively small amounts will produce death or other serious effects. These may be solid, liquid, or gas.
- C. Flammable. Such materials that will easily ignite, burn, and serve as fuel for a fire.
- D. Explosive. Although many explosive materials are also inflammable, these substances will explode under special conditions. Such materials must receive handling designed to eliminate exposure to or attainment of those conditions.

III. ROUTES OF INFECTIONS

Exposure in the laboratory to pathogenic microorganisms can occur in a number of ways. Most pathogenic organisms have a usual route of infection which produces the characteristic disease. However, when some agents are introduced by another route of infection, the disease produced may be atypical for that organism and difficult to diagnose unless the type of exposure is known by the attending physician. Exposure to infectious agents may occur in the following ways:

- A. Airborne. Pathogenic agents may become airborne through laboratory accidents, such as spills or breaking of containers. Some agents may become airborne simply by removing the caps or cotton plugs of culture tubes.
- B. Ingestion. The undesirable practice of mouth pipetting frequently results in exposure to pathogenic agents. Failure to wash hands after handling cultures or specimens may result in ingestion of the organism.
- C. Direct inoculation. Direct inoculation of agents sometimes occurs through accidents involving needles and syringes and broken glassware. Also, scratches or bites of laboratory animals may result in direct inoculation of pathogens.
- D. Skin contact. Some infectious agents can penetrate intact skin, while others may enter through the conjunctiva of the eye. Small cuts and scratches on the hands are very common and may provide a point of entry for pathogenic organisms.
- E. Vectors. Mosquitoes, ticks, fleas, and other ectoparasites are potential sources of laboratory infection unless properly contained, whether they are being used in laboratory transmission studies or happen to be present on wild animals brought into the laboratory for examination.

IV. POLICY

It is essential that every laboratory develop an emergency plan which covers contingencies which may arise from its use of dangerous materials.

The laboratory supervisor is responsible for the safety of all who enter his laboratory -- employees and visitors during the workday and building service personnel at other times. When work is hazardous, employees must be well trained in carrying out the laboratory's emergency plan, visitors must be kept out of dangerous areas, and service personnel must be assured that the laboratory is safe for them to enter and do their work. If the laboratory is not safe at the end of each day, signs prohibiting entry must be posted.

Since action must begin immediately following an accident, it is important that everyone in the laboratory be familiar with hazards that may accompany their work and with the laboratory's emergency plan developed as a safeguard in case of an accident. Supervisors are responsible for notifying employees accordingly.

V. PROCEDURES FOLLOWING EXPOSURE OR ACCIDENT

Because a detailed course of action could not be developed that was applicable in all situations, the procedures in this Guide are general and provide a foundation for division/program, branch, section, and unit levels to use in developing more specific procedures.

If assistance or additional information is needed, the CDC Biological Hazards Officer or the CDC Safety Officer should be contacted. The CDC Biological Hazards Officers' telephone extension is 3883. The CDC Safety Officers' telephone extension is 3837.

When accidents occur that could contaminate an area with dangerous chemicals or infectious agents, it is important that the following be done:

A. Get everyone out of the affected area at once.

B. Do not reenter until the extent of the hazard is determined.

1. Everyone must KEEP OUT of the affected area until there is no doubt concerning the safety to reenter. The employee must immediately notify the supervisor of the problem. The supervisor will determine if it is necessary to request assistance from the CDC Biological Hazards Officer or the CDC Safety Officer. If a hazard exists and the area must be entered, personnel from the CDC Biological Hazards Office and the CDC Safety Office can do so in protective clothing that allows them to work safely in contaminated environments.
2. The importance of keeping everyone out of the room where the accident occurred cannot be over emphasized. The only justification for immediately reentering such an area would be to save life or prevent a fire or explosion. In almost every instance, the hazard in the room will decrease as time passes.
3. If infectious agents are involved, at least one hour should be allowed for aerosols to be carried away and heavier particles to settle.

4. Chemicals spills may evaporate and be swept away rapidly, or may remain for a long time. Probability of fire or explosion is high when flammable solvents are spilled and ignition sources are present.

C. Determine the necessity for treating persons exposed to the dangerous agents. In addition to the usual first-aid measures, treatment may be necessary to:

1. Limit the damage due to chemicals or to terminate exposure to pathogenic organisms.
2. Decontaminate exposed personnel.
3. Restrict contamination to the smallest area.

Supervisors are responsible for referring persons exposed to pathogens to a PHS Outpatient Clinic, to a contract medical facility, or to another appropriate medical authority. The immediate supervisor of the person being treated is responsible for submitting appropriate forms and for ensuring that all information regarding the specific agent or isolate involved in the exposure is made available to the physician at the medical facility when the patient is admitted. (See Personnel Guides for Supervisors, Chapter IV, Guide 8.)

D. Post signs "DANGER, DO NOT ENTER, CONTAMINATED AREA" as described in Manual Guide--Safety Management No. CDC-2. Notify the CDC Biological Hazards Officer or the CDC Safety Office of the circumstances and that the sign has been posted.

E. Decontaminate the affected area. This may be carried out by the laboratory staff, or it may require special equipment and personnel from the CDC Biological hazards Office or the CDC Safety Office. The laboratory supervisor is responsible for requesting needed assistance. The supervisor must request assistance if there is any doubt regarding the extent of the hazard, or if there is any reason to believe that those persons doing the decontamination and clean-up will be in a hazardous situation.

CONTROL OF AIR FLOW IN LABORATORY AREAS

Section I. Purpose

II. Doors to Laboratories

III. Doors to Autoclave Rooms

I. PURPOSE

Safety in laboratory areas partially depends upon keeping infectious, toxic and flammable airborne materials in the laboratories where they originate. Controlling air flow helps accomplish this. This Guide provides policy and information pertinent to controlling air flow in CDC laboratory areas.

II. DOORS TO LABORATORIES

Doors to laboratories must be kept closed. CDC laboratory buildings are designed so that air moves from corridors into the labs. When the air flow is correctly balanced, air pressure in the corridor is higher than in the laboratories and the air flows rapidly under the doors and through the door slots into the laboratory. This rapidly moving curtain of air keeps airborne substances generated in the work areas from entering the corridors. This is especially important when infectious, toxic, or flammable agents are present. However, when a laboratory door is kept open, positive pressure in the entire corridor rapidly decreases, allowing airborne materials to be carried out of any laboratory on the corridor and into the hallway.

If the air does not flow from the hall into the laboratory when the door is closed, the Center Safety Officer, ext. 3837, or the Center Biological Hazards Control Officer, ext. 3883, should be contacted.

III. DOORS TO AUTOCLAVE ROOMS

Doors to autoclave rooms must not be blocked open. When these doors are open, odors and heat are released to the discomfort of everyone in the area.

USE OF LAMINAR AIR FLOW EQUIPMENT

Section I. General

II. Laminar Flow Clean Bench

III. Vertical Laminar Flow Biological Hood

I. GENERAL

Many microbiological hoods employ high efficiency filters and the laminar air flow principle to provide an ultra-clean work environment. Most of these devices are effective when properly used. Two types of laminar flow equipment, the laminar flow clean bench and the vertical laminar flow biological hoods, are discussed in this Guide.

The laminar flow clean bench protects the product from airborne contamination but does not protect the operator.

The vertical laminar flow biological hood protects both product and operator and may be used for agents of special hazard*. Safety and desirability of using this equipment to contain infectious material should be determined on an individual basis depending upon the agent, the proposed activity, and the need to prevent cross contamination.

Manufacturers' catalogs, reports of evaluations of laminar flow equipment and biological safety cabinets, and consultation regarding this equipment are available from the Center Biological Hazards Control Officer. Laminar flow equipment will be leak tested, adjusted or repaired by personnel of the Safety Office, upon request.

II. LAMINAR FLOW CLEAN BENCH

A large number of companies manufacture both vertical and horizontal laminar flow clean benches, intended only to protect the product or research work from airborne contaminants. Although one company may provide a better constructed unit than another, most of the commercially available equipment is adequate when:

- The High Efficiency Particulate Air (HEPA) filter has been tested and certified. To meet standards this filter should be at least 99.97 per cent efficient in removing particles 0.3 micron or larger by the di-octyl phthalate (DOP) test.

*(See Class 3 agents, Classification of Etiologic Agents on the Basis of Hazard -- DHEW, PHS, CDC Jan. 1970.)

- The HEPA filter housing has been properly sealed around the edges to prevent unfiltered air from bypassing the filter.
- The air flow is adjusted to 80-100 linear feet per minute.
- Proper technique is used to keep contamination generated by the microbiologist out of the research work.
- The pre-filter is periodically cleaned or replaced.

Because of the risk to personnel, work with infectious material on a laminar flow clean bench is not advisable. Use of clean benches should be limited to the preparation of sterile media, the assembly of sterile components into complete units (for example, membrane filters), the examination of sterilized equipment and materials for possible contamination, and similar operations. Work with live agents should not be permitted.

III. VERTICAL LAMINAR FLOW BIOLOGICAL HOOD

Work, including most microbiological manipulations, with organisms of special hazard*, can be safely performed in a properly designed vertical laminar flow biological hood. This hood, however, cannot replace the standard gastight Class III biological safety cabinet for extremely hazardous work.

Protection to the operator is comparable to what one might receive with an open-face biosafety cabinet with approximately 100 linear feet per minute flow of room air being drawn into the cabinet. (This is about the level of the protection provided in a CDC type biosafety cabinet with the glove panel on but without gloves in place.) The vertical laminar flow biological hood also provides a high degree of protection from contamination to the study material.

Since all biological hoods of this type take from 10% to 20% of the air passing through them from the room, it is necessary to exhaust this same amount from the cabinet. This exhaust air should be piped outside of the building or into the building air exhaust by means of an open thimble** if the building does not recirculate exhaust air. It is important that exhaust air from the biological hood not be vented into the laboratory.

Comments under Section II regarding testing of filters and proper techniques also apply to this equipment.

*(See Class 3 agents, Classification of Etiologic Agents on the Basis of Hazard -- DHEW, PHS, CDC Jan. 1970)

** (See working drawing of Biological Safety Cabinet -- DHEW, PHS, CDC Mar. 1966)

ACCIDENT REPORTING

Each employee is responsible for reporting to his supervisor:

- a. Each accident (both injury-causing and noninjury causing).
- b. Each accident resulting in damage to Government or private property.
- c. Each situation or condition observed on the job which has the potential for either injuring or endangering the health of employees and/or causing damage to property.

In case of injury, illness, disease, or exposure to infectious material or disease, the employee, or someone acting in his behalf, must complete Form CA-1 and forward it to his supervisor within 48 hours.

When an employee is injured on the job, the supervisor will arrange for prompt medical treatment as required. At the Clifton Road headquarters, injured employees will be referred to the PHS Outpatient Clinic; at Atlanta suburban locations and all field stations, injured employees will be referred to a local medical doctor or hospital as necessary. (In locations where emergency rescue services are available, the correct telephone number should be posted for ready reference.)

The immediate supervisor is responsible for reporting all accidents to the Office of Biosafety within five (5) working days. Use Form CDC 0.304, "CDC Accident Report." (This form must accompany, or follow immediately, each employee who is referred to the PHS Outpatient Clinic in Atlanta.) To properly document the accident for compensation, statistical, and accident prevention purposes, additional report forms may be required. The supervisor will be guided by information contained in Personnel Guides for Supervisors, Chapter IV, Guide 8-1, "Compensation For Injury," and Safety Management Manual Guide No. CDC-8, "Reporting Accidents, Incidents, and Injuries." The Office of Biosafety and the Personnel Management Office may be contacted for clarification and assistance.

Serious accidents shall be reported by telephone or telegraph within eight (8) hours of their occurrence to the Director, Office of Biosafety. Serious accidents are any accidents which result in:

1. Fatality.
2. The hospitalization or medical treatment (beyond first-aid) of three or more persons, including non-Federal personnel.

ACCIDENT REPORTING

3. The first-aid treatment of five or more persons, including non-Federal personnel.
4. Property damage exceeding \$25,000.
5. All aircraft accidents.
6. Radiation overexposure resulting in a disabling injury.
7. Biological exposure resulting in lost time or accidental release of biologicals which may involve the public.

LABORATORY ACCIDENT INVESTIGATION BOARD**Section I. Introduction****II. Board Membership****III. Responsibilities****I. INTRODUCTION**

Accidents in laboratories and infections resulting from work with etiologic agents must be reported to the CDC Safety Office on Form CDC 0.304, "CDC Accident Report," in accordance with manual Guide - Safety Management No. CDC-8, Reporting Accidents, Incidents, and Injuries. Prompt and thorough investigation of many of these incidents will identify the causes so that appropriate action can be taken to prevent similar accidents.

A Laboratory Accident Investigation Board has been established to investigate these accidents and infections.

II. BOARD MEMBERSHIP

The Laboratory Accident Investigation Board shall consist of three members:

- Two senior supervisory scientists who do mainly "bench work" -- appointed for two year terms.
- The Unit or Section Chief of the Organization in which the accident or incident occurred.

The members appointed for two years are:

Dr. Kenneth Walls
Dr. George Morris

III. RESPONSIBILITIESA. Board

The Board's overall responsibility is to make CDC laboratories safer places in which to work. This will be accomplished by:

- reviewing techniques, kinds, and uses of equipment involved in the accident;
- establishing the circumstances leading to the accident;
- other appropriate means to determine how similar incidents can be prevented from occurring.

The Board will neither assign responsibility nor recommend disciplinary action. Recommendations of the Board will be made to the Director, CDC.

B. CDC Safety and/or Biological Hazards Control Officers

The CDC Safety and/or Biological Hazards Control Officers will aid the Board by:

- selecting incidents for investigation;
- assisting in the investigation;
- serving as Secretary to the Board.

STORAGE OF FLAMMABLE SOLVENTS
IN CDC LABORATORIES

Section I. Purpose

II. Policy

III. Storage Cabinets

I. PURPOSE

This Guide establishes policy and describes cabinets for storing flammable solvents in CDC laboratories. In this Guide, flammable solvents are defined as liquid substances having a flash point below 140° F and having a vapor pressure not exceeding 40 p.s.i.a. at 100° F.

II. POLICY

Effective July 1, 1971, the following items will be stored in National Fire Protection Association approved-type solvent storage cabinets:

- All containers of flammable solvents larger than half-gallon.
- All flammable solvents supplies, when cumulative amounts greater than two gallons are kept in one laboratory room.

III. STORAGE CABINETS

Several sizes of cabinets have been made in the CDC shops, allowing a choice to fit funds and available space. Many laboratories may require storage of only a few solvents and the supervisors may wish to share cabinets with adjoining laboratories.

(III. Storage Cabinets - continued)

NFPA approved-type cabinets made at CDC are on display in the Safety Office (Building 8 at Clifton Road Facility). Information on delivery time, costs, and cabinet capacity is available there. In addition, commercially manufactured flammable solvent storage cabinets are sold by several laboratory supply firms. These larger boxes hold either 30 or 45 one-gallon containers.

Laboratory supervisors should determine their storage needs and order appropriately sized cabinets through regular channels from Engineering Services Branch or commercial suppliers. Cost of the cabinets will be borne by the user. Engineering Services Branch must have orders by April 1, 1971, to deliver the finished cabinets by July 1.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE

CENTER FOR DISEASE CONTROL

TO: All Laboratory Chiefs

DATE: July 21, 1970

FROM: Special Assistant to the Chief
Technical Services Section

SUBJECT: Flammable Solvents Requisition Form, HSM 0.616 (CDC)

Ref: Memo to all Laboratory Chiefs dated May 4, 1970, Institution
of New System for Procurement and Storage of Flammable Solvents

1. The attached Flammable Solvents Requisition Forms, HSM 0.616 (CDC), will replace Form PHS 0.507 (Stamped Flammable Solvents), and will be used in the future for ordering flammable solvents from List #1. This form is self-explanatory and the same instructions as previously issued will apply except your Control Account Number must be entered in the designated space on the new form.

2. Additional forms may be obtained from Mr. Talton, Laboratory Division Supply, Building D, room SSB-28.

Bonnie E. Smith
Special Assistant to the Chief
Technical Services Section

III. STORAGE CABINETS

Several sizes of cabinets have been made in the CDC shops, allowing a choice to fit funds and available space. Many laboratories may require storage of only a few solvents and the supervisors may wish to share cabinets with adjoining laboratories.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO Laboratory Chiefs

DATE: May 4, 1970

FROM Special Assistant to the Chief
Technical Services Section

SUBJECT: Institution of New System for Procurement
and Storage of Flammable Solvents

1. The laboratory fire and explosion in January 1969 instigated a reappraisal of flammable solvents procurement and storage procedures. Consequently, a new system has been devised for the procurement and storage of this category of solvents based primarily on safety needs, but with attention also focused on space limitations and operational economy and efficiency.

2. The System: Local suppliers have agreed to warehouse and deliver, at General Services Administration contract prices, on a regular daily basis (48 hours maximum lead time) most flammable solvents used by CDC. All solvents will be procured in volumes required for short term use; this precludes bulk storage. Since lead time for obtaining any flammable solvent will be practically negligible, the system in effect will substitute as CDC's flammable solvents warehouse without the attendant costs of space and manpower. Moreover, the suppliers will maintain inventory control, assuring the constant availability of flammable solvents.

3. Individual laboratories will order all flammable solvents on the attached lists through either Mr. Talton's office or Mr. Pinson's office (see paragraph 4 below for which solvents to order from which office). The Laboratory Division will pay for the solvents from funds provided by an already functioning open purchase arrangement.

4. In order to implement this system, the present Verbal Order Forms (PHS 0.507) with the words "Flammable Solvents" stamped on them will be used for ordering from List #1 until an appropriate form can be printed. (See instruction sheet.) If additional forms are needed they may be obtained from Mr. Pinson, Laboratory Services Unit. The Fisher Scientific Chemical Index will be used for ordering solvents on this form. Form 0.507 will be submitted to Mr. Talton, Laboratory Division Supply, Building D, room SSB 28. The orders received by Mr. Talton by 3 p.m. on Monday, Tuesday, Wednesday, and Thursday will be delivered the following day by the LSU along with regular glassware orders or by special delivery. Orders submitted on Friday will be delivered on Monday. ONLY the solvents on List #1 will be ordered on this requisition form. Solvents in the grades and container sizes on List #2 will be ordered on Form PHS 0.104 and submitted to Mr. Pinson, LSU, Building D, SB 20.

5. As uncomplicated as the system is, it cannot work without the full cooperation of all laboratorians in following a few basic guidelines:

- a. Maintain as small a supply of flammable solvents as is consistent with the efficient, uninterrupted operation of your laboratory activities--bearing in mind that these solvents are available on 24 hours notice (maximum 48 hours). It is expected that the CDC Safety Program will in the near future establish maximum on-the-shelf total quantity of flammable solvents at two gallons per room; all in excess of that amount will be required to be stored in special flammable solvents cabinets.
- b. When consistent with item a. above, order acetone, methanol, and xylylene (the three most widely used solvents) in quart containers instead of pints. The result will be a considerable saving on the base price of the solvents, of shelf space, and of man-hours used in deliveries. When usage is quite small; e.g., one pint per year, ordering by the pint would obviously be the wiser alternative.
- c. Use the lowest grade solvent that will satisfy your requirements. A high grade solvent can cost more than twice as much as a medium grade in many instances. The cumulative increased cost difference of using a high grade solvent when a lower grade would suffice can be considerable.

6. If the guidelines above are followed by all units using flammable solvents, the system will work quite smoothly. What is more important, laboratory safety will be greatly enhanced.

Bonnie E. Smith
Special Assistant to the Chief
Technical Services Section

FLAMMABLE SOLVENTS

LIST #1

<u>Fisher Catalog Number</u>	<u>Solvent</u>	<u>Grade</u>
A-18	Acetone	Cert-ACS
A-17	Acetone	NF
A-20	Acetone	CP
X-5	Xylene	Cert-ACS
A-412	Methanol	Cert-ACS
A-411	Methanol	Purified
B-245	Benzene	Cert-ACS
B-411	Benzene	Spectro
B-243	Benzene	Purified
T-324	Toulene	Cert-ACS
A-394	n-Amyl Alcohol	Cert-ACS
A-416	2-Propanol	Cert-ACS
A-414	1-Propyanol	Fisher-Cert
A-394	n-Amyl Alcohol	Fisher-Cert
A-399	1-Butanol	Cert-ACS
A-401	tert. Butanol	Cert-ACS
E-145	Ethyl Acetate	Cert-ACS
E-144	Ethyl Acetate	Anhydrous
E-189	Ethyl Acetate	Spectro
D-111	1,4-Dioxane	Cert-ACS
997-S	Ethyl Ether	Spectro
E-138	Ethyl Ether	Reag. ACS
E-139	Petroleum Ether	Cert-ACS
E-182	Methyl Cellosolve	Cert-ACS
M-209	Methyl Ethyl Ketone	Fisher-Cert
P-368	Pyridine	Cert-ACS
T-397	Tetrahydrafuran	Fisher-Cert
H-291	Hexane	Cert-ACS
H-300	Hexane	Pesticide
*	Hexane	Nanograde

*Grade equivalent unknown

<u>Fisher Catalog Number</u>	<u>Solvent</u>	<u>Grade</u>
C-556	Cyclohexane	Cert-ACS
C-555	Cyclohexane	Spectro
488-S	Acetonitrile	Spectro
A-391	Allyl Alcohol	Fisher-Cert
A-719	Amyl Acetate	Fisher-Cert
A-740	Aniline	Cert-ACS
C-573	Carbon Disulfide	Spectro
C-184	Carbon Disulfide	Cert-ACS
2215	Heptane	Highest Purity
M-203	Methyl Acetate	Fisher-Cert
2068	Propylene Oxide	Highest Purity
E-175	Dichloroethane	Cert-ACS
8178	Tetramethylethelene diamine	Highest Purity
C-407	Collodion	USP
A-401	tert. Butanol	
E-189	Ethyl Acetate	
D-111	1,4-Dioxane	
997-S	Ethyl Ether	
E-138	Ethyl Ether	
E-139	Petroleum Ether	
E-182	Methyl Cellosolve	
M-209	Methyl Ethyl Ketone	
P-368	Pyridine	
T-397	Tetrahydrofuran	
H-291	Hexane	
H-300	Hexane	
*	Hexane	

*Grade equivalent unknown

*Grade equivalent unknown

FLAMMABLE SOLVENTSLIST #2

FSN	SOLVENT	GRADE	UNIT
6810-753-4780	Acetone	ACS	1 lb bottle
6810-820-0496	Xylene	ACS	9.2 lb (gal.)
6810-753-4783	Methanol	ACS	1 lb bottle
6810-264-9080	Benzene	ACS	1 lb bottle
6505-104-8050	Ethyl Alcohol	USP	1 gal.
6505-104-9000	Ethyl Alcohol	USP	5 gal.
6505-105-0000	Alcohol, Anhydrous	USP	1 pt
6505-153-8225	Ethyl Ether	USP (for anesthesia)	1/4 lb can
6505-559-8383	Ethyl Ether	USP " "	1/2 lb can

When solvents of the above grades and unit sizes are needed, they MUST be requisitioned on form PHS 0.104. Additionally, alcohol must be ordered on a separate requisition and bear the authorized signature as required by the Laboratory Division Director's memo dated December 10, 1969. Combined orders of solvents, other than alcohol, on this list can be ordered on one requisition.

Submit completed requisition to Mr. Pinson, Laboratory Services Unit, Bldg. D, room SB-20. Laboratory Services Unit will have the requisition filled and deliver to the laboratories the following day.

If these solvents are required in a different grade and unit size than on this list (#2), they will be ordered from list #1 on PHS 0.507.

TO : All Laboratory Personnel
CDC Laboratories

FROM : Biological Hazards Officer and Safety Officer

SUBJECT: Storage and disposal of flammable solvents

Storage of solvents

Kitchen type refrigerators are used extensively in CDC laboratories. Some of these refrigerators have been modified to make them safe for storing flammable solvents; others have not. Non-modified refrigerators must not be used for storing flammable solvents.

If you have any doubts about whether a refrigerator has or has not been modified, ask Engineering Services, Ext. 3216, to examine it. Each refrigerator should have the proper sign on its door. Signs, obtainable from the Safety Office, read:

CAUTION. THIS BOX IS NOT EXPLOSION
PROOF, BUT INTERNAL WIRING HAS BEEN
MODIFIED TO PERMIT STORAGE OF WELL-
STOPPERED FLAMMABLE OR EXPLOSIVE
MATERIALS

and

DO NOT STORE ETHER, ACETONE, OR OTHER
VOLATILE OF FLAMMABLE MATERIALS IN
THIS LOCATION

Considerable confusion exists about using refrigerators to store flammable solvents. In many cases it is better to store them on well-ventilated open shelves. A refrigerator provides a cold, relatively safe place to keep some kinds of solvents - but safe only if the flash point of the solvent is above the temperature of the refrigerator. Ethyl ether, for example, has a flash point of -49°F and should not be kept in refrigerators. There are other disadvantages to refrigerator storage. Cold solvents pick up atmospheric moisture much faster when opened than those kept at ambient temperature. Also, cold does not retard the formation of peroxides in ethers. Then there is the problem of leaks or spills in refrigerators.

When these occur, evaporation takes place but the fumes are not carried away. Because the fumes remain in the box, it is very important that no ignition source be present when the door is opened.

Therefore, we do not recommend storing ether or other solvents with flash points below refrigeration temperature in modified refrigerators.

We do recommend:

1. The use of the smallest containers of flammable solvents compatible with your work.
2. Keep only the minimum supply on hand.
3. Anticipate spills and other accidents by removing all ignition sources **when** using flammable solvents; i.e., turn off burners, disconnect motors, heaters, etc.

Disposal of waste solvents

If waste solvents are miscible in water and the volume is less than a pint, flush down the drain, using large amounts of cold water. If not miscible in water, or in amounts greater than a pint pour waste solvents into a waste solvent can. The cans are listed in the GSA catalogue as items 7240-240-695 and 7240-655-4958. The Safety Office will empty the cans for you, on request.

If you have any questions about storage and disposal of flammable solvents, or other safety problems, call the Safety Office, 3837, or the Biological Hazards Officer, 3883.

Robert H. Huffaker

Robert Huffaker, DVM

Director, Office of Biosafety

EXPOSURE TO TERATOGENIC AGENTS
IN LABORATORIES

Section I. Purpose

- II. Female Employees of Childbearing Age
- III. All Other Employees

I. PURPOSE

This Guide sets forth policy regarding exposure to teratogenic agents in laboratories.

II. FEMALE EMPLOYEES OF CHILDBEARING AGE

A. General

Women of childbearing age, particularly women who are pregnant, must not be subjected to increased risk of exposure to possible or real teratogenic agents while employed or in training at CDC. In those circumstances where a risk exists, the woman is responsible for reporting pregnancy to her supervisor so that appropriate action can be taken.

B. Restrictions

1. All Women of Childbearing Age

Women of childbearing age, regardless of marital status, must present positive serologic evidence of past rubella infection or successful immunization to rubella before they shall be permitted to work in laboratories where live rubella virus is being used.

Similarly, women of childbearing age must possess positive serologic evidence of previous cytomegalovirus (CMV) infection before working in laboratories where CMV is being used.

2. Pregnant Women

No live virus vaccine should be administered to a pregnant employee. If a pregnant woman is required to receive a live virus vaccine to perform her duties, she should be excluded from these duties during her pregnancy.

Laboratory exposure to radioactive materials should be avoided completely during pregnancy.

Since no information on the potential teratogenic effects of most microorganisms is available, the risk of laboratory infection with any microorganisms should be kept to a minimum during pregnancy. This restriction also applies to exposures to Australia Antigen (Hepatitis Associated Antigen - HAA) containing materials from which hepatitis infection might result. Those viruses to which the woman is known to be immune (that is, by serologic testing) can be safely worked with. Viruses or other microorganisms to which the woman is not known to be immune should be handled only under generally acceptable safe conditions (that is, inoculation of in vitro cultures, serology, etc.). Depending on the agent involved, work with such microorganisms which involves animal inoculation or infectious aerosols should be kept to a minimum or entirely eliminated.

III. ALL OTHER EMPLOYEES

No restrictions need be imposed on male employees or postmenopausal female employees for assignment to work areas where exposure (real or potential) to teratogenic agents exists. It is desirable, however, that these employees be tested serologically for evidence of past infection with the agents involved and that they promptly report to their supervisor any illness possibly related to their work assignment.

III. PROCEDURES

A. Preliminary Discussion

The investigator should contact the Biological Hazards Control Officer to determine if Form HSM 3 (A) will be necessary for the proposed work and, if so, to obtain the form.

CDC TN-71.3 4/30/71

5/15/74

TRANSMITTAL NOTICE - SAFETY MANAGEMENT

CIC TN-74.3

PEN-AND-INK CHANGE

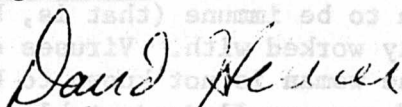
The following paragraph should be added to Manual Guide - Safety Management No. CDC-11, dated 4/30/71.

On page 2, between the second and third paragraphs under No. 2, Pregnant Women, insert the following:

During pregnancy, a woman should not be permitted to work with live Toxoplasma gondii, or to have any contact with the living organism.

FILING INSTRUCTIONS

Post receipt of this Transmittal Notice on the Check List of CDC Transmittal Notices - Safety Management.



David J. Sencer, M.D.
Assistant Surgeon General
Director, Center for Disease Control

DISTRIBUTION: Mailing List No. 1, Code 2

USE OF HAZARDOUS BIOLOGICAL AGENTS

Section I. Purpose
II. Use of Form
III. Procedures

I. PURPOSE

This Guide describes the use of Form HSM 3.614 (CDC), Notice of Intent to Work With a Hazardous Biological Agent (Exhibit 1), and provides procedures for submitting and processing the form. It is available from the CDC Biological Hazards Control Officer, telephone extension 3883.

II. USE OF FORM

Form HSM 3.614 (CDC) should be used when an employee (investigator) plans a hazardous laboratory project or procedure, e.g.:

- An existing technique is to be modified and the investigator believes that the modification may increase the risk to laboratory personnel or animal caretakers.
- An antigen, whose risks are well understood by the investigator, is to be highly concentrated with possible increased risk.
- An infectious agent is to be used which makes immunization of personnel desirable, prior to onset of work.
- A new technique, new agent, or new operational procedure is to be used which will make necessary a review of the hazard and containment.

Generally, the form will be used when the investigator wants the CDC Biological Hazards Control Officer to review the safety and containment plans, or when the investigator plans work that will require immunization of personnel. The use of the form will be highly desirable if the possibility of injury to staff members or others will be at all greater than for routine procedures.

III. PROCEDURESA. Preliminary Discussion

The investigator should contact the Biological Hazards Control Officer to determine if Form HSM 3.614 (CDC) will be necessary for the proposed work and, if so, to obtain the form.

(III. continued)

B. Submission of Form

The investigator should submit one copy of the completed form through administrative channels to the Biological Hazards Control Officer. Simultaneously, the investigator should send another copy directly to the Biological Hazards Control Officer for his advance information. The form must be submitted early enough to allow the Biological Hazards Control Officer to contact supervisors of all personnel who will be at risk to assure that they will be immunized before the work with the pathogenic agent begins. The investigator should allow at least three weeks for immunizations to be accomplished; longer periods may be required for some agents.

C. Processing of Form

When the Biological Hazards Control Officer receives the notice, he and the investigator together will evaluate the project protocol, equipment, work space, and other pertinent information for safety. The Biological Hazards Control Officer then will write a report in which he will define the conditions for project approval. He will send a copy of the report to all personnel who need information about the work, e.g.:

- the investigator.
- the chiefs of organizational entities whose personnel will require immunizations or will be restricted from entering the area.
- the Medical Officer in Charge of the U.S. PHS Outpatient Clinic who is to be informed when new agents will be studied at the Center.
- the CDC Safety Officer.

D. Clearance to Begin Work

If immunizations will not be required and if the work hazards will be satisfactorily controlled, the Biological Hazards Control Officer will inform the investigator of clearance to begin work with the hazardous biological agent.

If immunizations will be required, the Biological Hazards Control Officer will notify the investigator as soon as immunization completion dates are known.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE

Date:

Reply to

Attn of:

Subject: Notice Of Intent To Work With A Hazardous Biological Agent

To: Biohazards Control Officer, CDC
THROUGH:

Name and strain of agent _____

Inclusive dates of work _____

Brief description (methods, equipment, etc.) _____

Laboratory work will be done in Building _____, Room _____

Animals will be housed in _____

Animal species to be used _____

Routes of inoculation _____

Will infectious aerosols be used? _____ Will arthropods be used? _____

_____ Who reviewed and approved protocol for safety of all

personnel? _____ Are human immunizing

agents available? _____ Has authorization to immunize your staff

been requested from Center Director? _____ Were immunizations

authorized? _____ Should other CDC staff (engineering, technical

services, etc.) be immunized? _____ Will terminal decontamination

of laboratories and/or animal holding areas be required? _____

HSM 3.614 (CDC)
3-69



This memo must be submitted early enough to allow the Biohazards Control Officer to contact supervisors of all personnel who will be at risk to assure that they will be immunized before work with the pathogenic agents begins. Allow at least three weeks; longer periods may be required for some agents. As soon as immunization completion dates are known, the investigator will be notified.

If immunizations are not required and if work hazards are satisfactorily controlled, clearance to begin work will be sent to the investigator by the Biohazards Control Officer.

The Biohazards Control Officer also will notify the following individuals, as appropriate, of the proposed work:

- Chief, Scientific Services Section
- Chief, Technical Services Section
- Chief, Engineering Services Branch
- Safety Officer
- Medical Officer, USPHS Clinic

ELECTRICAL SAFETY

- Section I. Introduction
II. Responsibilities
III. Safe Work Methods and Procedures

I. INTRODUCTION

This Guide places responsibilities and establishes safe work methods and procedures for electrical safety.

The hazards inherent in electrical work dictate that common sense and good judgment be exercised at all times. The safety of an employee takes precedence over all other requirements. The procedures included in this Guide are intended to be minimum requirements only since it is obviously impossible to include all common-sense precautions for performing safe electrical work. However, the absence of a written safety rule does not relieve the employee or his supervisor from using good judgment in carrying out work assignments. If conditions exist which are not fully understood by the employee performing the work, he will consult his immediate supervisor regarding safe work methods before proceeding. New electrical installations and maintenance, replacement, modification, repair, or rehabilitation of existing facilities must comply with the latest version of the National Electrical Code (NFPA 70-1971).

Failure to wear or use officially prescribed protective equipment or to follow safe work procedures prescribed by competent authority will be grounds for disciplinary action. The nature of disciplinary action taken will depend on the circumstances in an individual case and may include admonishment, reprimand, suspension, or separation.

II. RESPONSIBILITIES

The supervisor is responsible for the general safety of the employees under his supervision. This includes responsibility for temporary or other employees who do not regularly work under his direct supervision. The supervisor will designate safe methods to do the jobs and teach these methods to the employees. Also, the supervisor will ensure that the employees:

- Are qualified and capable of doing the jobs assigned to them.
- Wear the necessary safety equipment at all times.
- Properly use the equipment and follow the prescribed methods for their jobs, including the applicable requirements of the National Electrical Code and the safe work methods and procedures in this Guide.

The employee and his co-workers are primarily responsible for their safety. Each individual is responsible for being alert at all times to the progress and condition of the work being done around him. The supervisor's responsibility in no way relieves any employee from his individual responsibility to perform his work safely.

The employee and the supervisor share the responsibility for the safe condition of all equipment and tools, both personal and CDC owned. The employee will constantly observe the tools and equipment he uses and will immediately report any defects to his supervisor. Periodically, the supervisor will inspect all the equipment and tools for safe and serviceable condition.

III. SAFE WORK METHODS AND PROCEDURES

A. Work Area Inspections

The supervisor will:

- Determine what safety equipment is required, have it available before work begins, and ensure that it is used at all times as described in this Guide. If sufficient or proper equipment is not available to make the job safe, he will obtain correct equipment before proceeding. He will not improvise.

III. SAFE WORK METHODS AND PROCEDURES (Continued)A. Work Area Inspections (Continued)

The supervisor will: (Continued)

- Hold an "on site" conference with his employees before the work begins. He will review the details of the job to be done, point out each employee's responsibilities, and discuss the hazards of the job and the way to protect against them.

The employee will:

- Inspect the general work area before beginning work to recognize any possible hazards.
- Visually check before opening compartments or chambers housing energized conductors to determine if unusual conditions exist.

B. Electric Switches

Unexpected operation of electrical equipment that can be started by remote control may cause injuries to persons who happen to be near enough to be struck. Also, unexpected starting of motors may injure employees working on them as well as the employees operating machines controlled by the motors.

When repairing a motor or other electrical equipment, the employee will ensure that:

- The circuit is opened at the switch box.
- The switch is padlocked in the "off" position and tagged with a description of the work being done, the name of the employee, and the department involved.
- The key to the padlock remains in the possession of the employee doing the work.

Because of the grave risk to life from uncontrolled maintenance work, the supervisor will ensure that:

- NO WORK IS DONE ON "HOT" LINES* WITHOUT THE APPROVAL OF THE CHIEF, ENGINEERING SERVICES BRANCH.
- All maintenance employees are drilled on lockout routines.
- The lockout routine is implemented with the necessary keys, locks, and arrangements.

* Any circuit energized with 100 or more volts.

III. SAFE WORK METHODS AND PROCEDURES (Continued)B. Electric Switches (Continued)

The following is a lockout procedure which is generally acceptable.
The employee will:

- Alert the operator.
- Check each engine or motor, line shaft or other power transmission equipment, or power-driven machine before starting to work on it to ensure that it cannot be set in motion without his permission.
- Place his own padlock on the control switch, lever, or valve, even though someone has locked the control before him. He will not be protected unless he puts his own padlock on it.
- Remove his own padlock when through working at the end of his shift. He should never permit anyone else to remove it for him. When removing his padlock, he should be sure he is not exposing another person to danger.
- Immediately report the loss of the key to his padlock to his supervisor and get a new padlock.

C. Fuses and Circuit Breakers

The National Electrical Code requires the placement of a switch in the circuit that can be opened to de-energize fuses or circuit breakers. As an added precaution, CDC requires the use of insulated fuse pullers.

The employee will:

- Before replacing the fuses, lockout the circuit and make an investigation to determine the cause of the short circuit or overload.
- Replace blown fuses by others of the same type and size.
- Never insert fuses in a live circuit.

D. Grounding

The employee will:

- Follow the applicable requirements of the National Electrical Code.

III. SAFE WORK METHODS AND PROCEDURES (Continued)D. Grounding (Continued)

The employee will: (Continued)

- Ground the neutral point of all secondary circuits of alternating current distribution systems (of not more than 150 volts to ground) at the building service, at the switchboard, or near the transformer.
- Ground the frames of all electrical tools (other than approved double-insulated tools and tools powered by portable or truck-mounted electrical generators) to an effective ground to prevent electrical shock due to the failure of the insulation between the current-carrying parts and the metal frame of the tool.
- Bond the frames of all electric tools (other than approved double-insulated tools), when powered by portable or truck-mounted generators, to the frame of the generator, to prevent potential difference between the tool and the generator frame or any other object with which the generator may be in contact.
- Ground or bond portable electric tools and equipment with approved type three conductor rubber covered cord; connect one end of the third wire in this cord to the metal frame of the tool and the other end to a known ground.
- Bond together the motor base and frame of stationary tools and equipment used in shops or permanent locations and effectively ground them to a known ground.
- Make extension lamp cords for general use of heavy duty rubber covered or other approved insulated cord, rubber covered attachment plug, and keyless rubber protection lamp socket with guard.
- Never use electric tools with cords while working on or within reach of energized transmission and primary distribution conductor regardless of the type work being done.

E. Personal Protective Equipment

The supervisor will:

- Ensure that all tools and personal protective equipment used by his employees meet or exceed the applicable standards listed in Chapter 8-00-40 of the DHEW Safety Manual. He will obtain written approval from the CDC Safety Officer for variances and exceptions to these standards.

III. SAFE WORK METHODS AND PROCEDURES (Continued)E. Personal Protective Equipment (Continued)

The supervisor will: (Continued)

--BEFORE ASSIGNING WORK ON "HOT" LINES, OBTAIN APPROVAL TO DO THE WORK FROM THE CHIEF, ENGINEERING SERVICES BRANCH.

--Ensure that rubber gloves and sleeves are given complete electrical testing every six months in accordance with the appropriate American Society for Testing and Materials (A.S.T.M.) standards.

--Ensure that employees under his supervision use the following protective equipment in work situations as described in this Guide: electrician's hat or bump cap, safety belts, rubber gloves and glove protectors, rubber sleeves, insulating blankets, insulating line hose, insulating hoods and dead-end protectors. This equipment is available at CDC. He will obtain other needed protective devices and equipment.

The employee will:

--Before working on "hot" lines, ascertain that approval to do so has been obtained from the Chief, Engineering Services Branch.

--Wear rubber gloves (low-voltage and linemen's) for protection from electric shock and burn through hand contact. He will wear low-voltage gloves when the exposure is less than 750 volts and linemen's gloves for higher voltages. Linemen's gloves are available in three classes, depending on the voltage to be protected against.

--Wear rubber sleeves for protection from electric shock and burn to arm and shoulder areas.

--Use insulating blankets to cover electrical conductors, insulators, and equipment in a work area to protect against electrical contact. These blankets are available in different sizes and designs.

--Use insulating line hose to cover electrical conductors in or near a work area to protect against accidental contacts.

--Inspect all rubber protective equipment before each use for punctures, cuts, cracks, deterioration or other damage which might render it unsafe.

III. SAFE WORK METHODS AND PROCEDURES (Continued)F. Overhead Systems

The employee (lineman) will:

- Wear rubber gloves and sleeves on both hands at all times when working on or within reach or extended reach (hand reach extended by a conductive item supported by hand) of energized circuits or any wire or apparatus that may become energized by remote or accidental means, even though protective equipment is in place.
- Adequately and securely cover grounded and low voltage equipment within reach of the energized work area. (Experience has shown that the second point of contact, such as neutrals, ground wires, grounded guys, apparatus, and secondary wires must always be covered with protective equipment to provide a complete protection from primary shocks. If this second contact is prevented, a serious personal injury will probably be avoided.)
- Apply the necessary protective equipment when he reaches the first conductor to be covered, such as a secondary or ground conductor. (Special containers not only allow for raising and lowering equipment safely, but serve as receptacles for holding the protective goods when the employee changes the pattern of protection.)
- Cover all conductors and equipment with which any contact is possible as he advances to his working position (within normal reaching or direct falling distance). He should not, at any time, pass or reach through or beyond any energized equipment before covering it with protective equipment.
- Take care, when installing protective equipment and as work is progressing, to prevent damage to the protective equipment from such things as tie wires, armor rods, climber gaffs, wood splinters or sharp tools. He must not remove rubber gloves and sleeves while in an energized working area, even though all conductors have been covered.
- Remove first the topmost and most distant protective devices (when all work is completed and protective devices are to be removed) and place them in a container for lowering. He should never drop protective equipment, throw it to the ground, or allow it to ride down a handline. He should wear a hard hat, rubber gloves, and sleeves until he is entirely clear of the energized area.

III. SAFE WORK METHODS AND PROCEDURES (Continued)G. Live Line Tools

The supervisor will obtain information from the CDC Safety Officer on the care, maintenance, and retesting of live line tools.

The employee will:

- Thoroughly inspect live line tools before each use.
- Not use live line tools in rain or heavy fog except in emergency work; in those cases, he should use rubber protective equipment.
- Choose a safe working position on the structure and check it carefully before changing his position. He should work as far below the conductors as practical and, if possible, avoid positioning himself directly below the conductors.
- Never come in contact with structure guys or metallic fences in an area where work is being done on live lines, when the employee is on the ground.
- Remove, set out, or cover all metallic paths to ground within reaching distance, if the employee is working on a wooden pole. (Induced voltage or static in metallic hardware can cause severe shock to employees on some wooden poles. Such hardware should be covered or avoided. Employees using live line tools on steel towers are considered grounded at all times; on extremely high-voltage lines, employees can use conductive devices to improve this ground contact.)
- Never place his hands closer than is absolutely necessary to the energized line or the metal parts of the live line tool he is using.
- Use extreme caution when working with live line tools. He should smoothly and evenly move all tools and conductors, using blocks and tackle to help attain smooth movement.
- Give particular attention to positioning of tools when sharp angles and large conductors are to be worked. He should use additional equipment when needed to minimize stress on individual tools.

III. SAFE WORK METHODS AND PROCEDURES (Continued)G. Live Line Tools (Continued)

The employee will: (Continued)

- Remove from service tools that show a static discharge.
- Securely fasten hold-out ropes or live line tools being used to spread or raise conductors. He should not touch these ropes except to secure or release them. Also, he should not use ropes on conductors carrying high voltage unless the rope is insulated with a tested line stick.
- Treat temporary bypass jumpers, although insulated, as "hot" at all times. He should keep them clear of the structure, the pole hardware, and himself.
- Work only one wire at a time on the same structure, except in the case of a crossarm operation when several conductors are moved as a unit.
- Tie securely the tools to be raised or lowered to the hand line or place them in an appropriate bag.
- Never lay live line tools on the ground. He should always place them on canvas tarpaulin or specially constructed racks.
- Reserve blocks, ropes, and slings used for live line work for that purpose only. He should keep ropes free of dust, moisture, oils, and acids and store them in the same manner as live line tools.
- Wear personal protective equipment, such as hard hats, rubber gloves, and rubber sleeves at all times when working with live line tools.
- Inspect live line tools regularly for excessive wear and for indications of having been overstressed, and retest them every six months.

USE OF VACUUM EQUIPMENT

Section I. Introduction II. Safety Procedures

I. INTRODUCTION

Although frequently forgotten or overlooked, it is common knowledge that glass containers used in vacuum filtering as vacuum traps may burst and shower the area with glass and the contents of the vessel. Therefore, each employee using vacuum equipment should follow the safety procedures in Section II.

II. SAFETY PROCEDURES

Use metal flasks, Dewars, etc., when possible.

Always wear safety glasses, goggles, or a face shield.

When using glass containers, take one of the following precautions:

- Tape the flask with duct tape, adhesive tape, or a similar product.
- Put the flask in a metal container tall enough to hold the entire flask.
- Place a safety shield between the flask and personnel. This is fairly effective if the flask is in a fume hood, or similar isolated position, but it is not satisfactory on an open bench.

MOUTH PIPETTING

- Section I. Introduction
II. Policy
III. Precautionary Measures

I. INTRODUCTION

Mouth pipetting of infectious agents and of toxic or corrosive chemicals is extremely hazardous. Infections and injuries directly attributable to mouth pipetting have been widely documented; for example, serum from hepatitis cases has been implicated repeatedly as a source of infection for laboratory personnel.

II. POLICY

Mouth pipetting of material containing etiologic agents, of sera, of toxic or corrosive chemicals, and of other known hazardous materials is strictly forbidden. Effective hand-pipetting devices are available and must be used when any element of risk exists.

III. PRECAUTIONARY MEASURES

Demonstrations of safety pipetting devices and techniques can be arranged through the Employee Development Section, Personnel Management Branch, telephone number 633-3311, extension 3457.

The Office of Biosafety has reference material which defines etiologic agents and has recommendations for working safely with them.

CONFINED SPACES - INSPECTION AND ENTRY

- Section I. Introduction
II. Responsibilities
III. Inspections Prior to Entry Into Confined Spaces
IV. Entry Into Confined Spaces
V. Welding and Other Open-Flame Work
VI. General Precautions

I. INTRODUCTION

Confined spaces are areas which, due to their physical characteristics and/or inadequate ventilation, may contain hazardous atmospheres (flammable or toxic gases, or insufficient oxygen). Examples are fired and unfired pressure vessels, ducts, tanks, tunnels, vaults, pits, compartments, boilers, sewers, and manholes. Most of them must be entered occasionally by maintenance personnel.

A principal hazard in confined spaces is lack of oxygen. However, mechanical, electrical, chemical, or other hazards may exist or develop. For these reasons, specific precautions must be observed when entering a confined space.

CONDITIONS IN A CONFINED SPACE MUST BE CONSIDERED HAZARDOUS TO LIFE UNTIL PROVED OTHERWISE. This cardinal rule of safety applies in every case of entry into a partial or complete enclosure wherein oxygen may be seriously deficient or dangerous concentrations of air contaminants may collect.

The "Boiler and Pressure Vessel Code," published by the American Society of Mechanical Engineers, contains detailed specifications concerning the design, construction, testing, and installation of boilers and unfired pressure vessels. (A copy of this Code is available in the CDC Safety Office.) Information from this Code and other sources has been used to prepare this Guide. The principles discussed are applicable to all work in any confined space at the Center for Disease Control.

II. RESPONSIBILITIES

A. Office of Biosafety

The Office of Biosafety is responsible for determining the condition of the atmosphere in confined spaces at CDC facilities in the Atlanta area before personnel enter the areas. (Supervisory personnel in field stations are responsible for assuring compliance with the requirements of this Guide. The CDC Safety Officer should be consulted for guidance.)

B. Supervisor

The supervisor of the work force is responsible for the safety of the employees under his supervision. Before any employee is allowed to enter confined areas, the supervisor must assure that:

- All necessary safety tests are performed before entry into confined areas.
- All workers are familiar with the operation to be performed.
- All workers recognize the hazards which may be encountered and are familiar with emergency procedures.
- All necessary safety equipment is provided and is in proper working condition.

C. Employee and Co-workers

The employee and his co-workers are primarily responsible for their own safety. Specifically, each employee must:

- Follow safe work procedures.
- Follow the instructions of his supervisor and safety officials.
- Properly use the safety equipment which is provided.

III. INSPECTIONS PRIOR TO ENTRY INTO CONFINED SPACES

A. General

Before anyone enters into any confined area, the supervisor of the work force must obtain approval from an official of the Office of Biosafety.* Personnel of that Office will determine the condition of the atmosphere in the area. If necessary, they will arrange for the necessary tests to be performed to determine the oxygen content of the space and to detect the presence of toxic and/or explosive gases or vapors.

B. Preparation of Pressure Vessels

Before boilers and other pressure vessels are inspected internally, they must be properly prepared by draining, ventilating, and cleaning. The supervisor must inform the inspector of corrosive, poisonous, or toxic substances which have been in the vessel. The cleaning method will depend on the use of the vessel. If it has contained petroleum or chemical products, the vessel may be filled with water, a caustic solution, or a neutralizing agent to remove sludge and adhered materials. Vessels used for flammable liquids should be washed, steamed, and/or ventilated, until tests by the Office of Biosafety* personnel indicate the level to be safe.

C. Tests of Atmosphere

Forced ventilation with fresh or certified breathing air must be used to insure that the atmosphere in the vessel remains safe. Tests of the atmosphere must be made at 30-minute intervals to assure that conditions remain safe while workmen are in any confined area.

D. Final Inspection

After all preparations have been made, the supervisor of the work force must verify that:

- The vessel is safe.
- All lines are closed and locked out.
- All power sources are locked out.
- Ventilation and personal protective equipment are adequate.
- Safe work procedures are planned.

Only then may the supervisor authorize inspectors or other workmen to proceed. No one may enter the area without authorization of the supervisor.

*Field station supervisors should consult the CDC Safety Officer for guidance.

III. INSPECTIONS PRIOR TO ENTRY INTO CONFINED SPACES (Continued)E. Lockout Procedures

Valves on piping both into and out of the vessel must be closed, locked out, and tagged to prevent operation. All power-driven devices (such as agitators) must be disconnected and locked out.

The following is a lockout procedure which is generally acceptable:

The supervisor will determine the unit to be taken out of operation.

The appropriate employee will:

- Turn "off" the point of operation controls.
- Turn "off" the main power controls (switch, breaker, or valve).
- If involved in the job, snap his lock on the control lever or on a multiple-lock adapter after the switch has been opened and the valves closed. Attach to the lock a tag giving his name, his supervisor's name and the reason for the lockout (i.e., type of work being done).
- Try the disconnect or valve to make sure it cannot be moved to the "on" position.
- Try the machine controls as a test that the main controls are "off."
- Remove his own lock and tag as he completes his portion of the assignment.
- If last to complete his assignment, notify the supervisor that the work is finished and that the equipment is ready for use.

IV. ENTRY INTO CONFINED SPACES

Inspectors or workmen must not be lowered into any confined space without facilities for them to climb out. Straight ladders or rope or chain ladders with rigid wood rungs must be provided.

Inspectors or workmen must not be required to go into an opening that they must squeeze through since they cannot be removed quickly in an emergency.

IV. ENTRY INTO CONFINED SPACES (Continued)

In some situations, the supervisor or safety officials may direct the inspector or workmen to wear safety equipment (such as self-contained breathing equipment and/or a safety harness attached to a lifeline) when entering a confined space.

An observer wearing identical equipment must be stationed outside the area. He must be able to communicate with the employee inside the confined space. Also, he must have some device, such as a squeeze-bulb horn, for signaling for additional help. Depending on the previous use of the area, the inspector must be required to use a vapor-proof flashlight or a vapor-proof low-voltage extension light.

V. WELDING AND OTHER OPEN-FLAME WORK

Maintenance work requiring welding or open flame, where toxic metal fumes (such as cadmium, chromium, or lead), may be needed. If so, it must be done only with sufficient local exhaust ventilation to prevent the creation of a health hazard or be done only by workmen wearing respiratory protection approved by officials of the Office of Biosafety.

Welding or the use of open flames near any solvent cleaning equipment must not be done unless the equipment has first been thoroughly cleared of solvents and vapors.

When arc welding is to be suspended for any substantial period of time, the workmen must remove all electrodes from the holders, locate the holders carefully so that accidental contact cannot occur, and disconnect the machine from the power source.

When gas welding or cutting is to be suspended for any substantial period of time, the workmen must close the torch valves and close the fuel-gas and oxygen supply to the torch at some point outside the confined space. When practical, the torch and hose should also be removed from the confined space.

VI. GENERAL PRECAUTIONS

General precautions for working in confined spaces are to:

- Notify the Office of Biosafety before beginning work.
- Have proper ventilation, equipment, and personal protection.
- Lockout all switches, valves, etc.
- Assure adequate means for emergency escape or rescue of the intended occupants.

VI. GENERAL PRECAUTIONS (Continued)

General precautions for working in confined spaces are to: (Continued)

-- Constantly observe men working in confined spaces.

-- Diligently enforce fire safety rules.

Ventilation can be provided by portable power-driven blowers operated outside the area with canvas tubes leading inside. It may be possible to operate draft fans for short periods of time to provide adequate ventilation.

All electrical tools should be properly grounded and, along with extension cords, should be thoroughly inspected before use.

Necessary personal protective equipment for work in confined spaces may include any or all of the following: hard hats, goggles, dust respirators, self-contained breathing equipment, heavy leather-palmed gloves, safety shoes, and safety harness with attached lifelines. These are available from the Engineering Services Branch Stock Room and/or the Safety Office.

LOCKOUT METHODS

- Section I. Introduction
II. Definitions
III. Policies
IV. Responsibilities
V. Lockout Equipment
VI. Lockout Procedures

I. INTRODUCTION

An employee who repairs, adjusts, or maintains machinery or other equipment is subject to injury unless he is certain that the machine or equipment cannot be started, energized, or activated until his job is complete. The use of lockout devices and lockout procedures provides the most practical and positive guarantee that no one will be injured while performing such work.

This Guide establishes policies, assigns responsibilities and explains methods for locking out switches, breakers, valves, or other power controls.

Failure to enforce or follow the procedures outlined in this Guide will be grounds for disciplinary action. The nature of the disciplinary action taken will depend on the circumstances in an individual case and may include admonishment, reprimand, suspension, or separation.

II. DEFINITIONS

- A. Lockout Device: A mechanism that allows the use of padlocks to hold a switch lever or valve handle in the "off" position. Some switches and valves have lockout devices built in; others require modification or the use of special equipment before padlocks can be used.
- B. Lockout Procedure: Steps that must be taken to assure that power controls are locked in the "off" position.

III. POLICIES

Lockout devices and lockout procedures must be used in every situation that requires maintenance men, repair men, electricians, pipefitters, or other craftsmen to work on potentially hazardous equipment. Some examples of such situations are:

- Cleaning, oiling, or repairing movable parts on large machines.
- Clearing blocked or jammed mechanisms.
- Working on high pressure steam lines or lines carrying hazardous substances.
- Inspecting boilers or other pressure vessels.
- Installing or repairing electrical equipment.

IV. RESPONSIBILITIES

A. Supervisor

The supervisor is responsible for the general safety of the employees under his supervision. He must ensure that all employees:

- Understand the tasks to be done.
- Are aware of potential hazards.
- Are familiar with emergency procedures which may be required.
- Wear the necessary safety equipment.
- Properly follow the lockout procedures of this Guide.

Also, the supervisor must provide the necessary devices and equipment for following the lockout procedure.

B. Employee and Co-workers

The employee and his co-workers are primarily responsible for their own safety on the job. Each employee must be alert at all times to the progress and condition of the work being done around him. Also, he must know and follow the lockout procedure.

V. LOCKOUT EQUIPMENT

Lockout devices, padlocks, and tags are available at the following locations:

- Clifton Road - Engineering Services Branch Supply Room
(Mr. Webster L. Powell)
- Electrical Shop (Mr. Donald G. McClure)
- Chamblee - Building 19 (Mr. Howard C. Davis)
- Lawrenceville - Building C (Mr. Jay C. Sager)

Equipment will be issued only to supervisors. The supervisor will immediately remove one of the keys from each padlock which is issued to him and retain it in his possession until he returns the padlock and both keys to stock. Each workman who receives a padlock will receive only one key.

If one of the keys is lost, the lock and the extra key must be destroyed or the tumblers changed and two new keys provided. The equipment custodians named above are responsible for initiating this action, when required.

VI. LOCKOUT PROCEDURES

Before any equipment is locked out, the appropriate supervisors of Engineering Services Branch and of the area where the equipment is located must agree on the specific machine, unit, or circuit to be taken out of operation.

Prior to the initiation of the lockout procedures, the Engineering Services Branch supervisor must inform the user of the equipment or the supervisor of the area in which the equipment is located.

Engineering Services Branch personnel locking out the equipment will:

- Turn off the point-of-operation controls. (Do not pull disconnect-switches while they are under load because of the possibility of arcing or explosion.)
- Turn off the main power controls (switch, breaker, or valve).

VI. LOCKOUT PROCEDURES (Continued)

Engineering Services Branch personnel locking out the equipment will: (Continued)

- Snap his lock on the control lever or lockout device (multiple lock adapter) after the switch has been opened or the valve closed. Attach to his lock a tag containing his name, type of work being done, and his supervisor's name. (NOTE: This applies to each employee who will be involved in the work.)
- Try the disconnect switch or valve to make sure it cannot be moved to the "on" position.
- Try the machine controls before starting to work as a test that the main controls are "off."
- Remove his own padlock and tag when he completes his work. (NOTE: He must not permit anyone else to remove his padlock. Also, he must not remove anyone else's padlock.)
- If the last employee to remove his padlock, notify the Engineering Services Branch supervisor that the work is completed.

The Engineering Services Branch supervisor will:

- Notify the user of the equipment or the supervisor of the area in which the equipment is located that the equipment is ready for use.
- Collect all lockout equipment (padlocks, multiple lock adapters, tags). If reusable, return them to stock. If unusable, discard them.

DISTRIBUTION OF CULTURES OF MICROBIAL AGENTS
AND OF VECTORS

Section I. Purpose
II. Policies and Procedures

I. PURPOSE

This Guide sets forth policies and procedures governing the distribution of cultures of pathogenic and nonpathogenic bacterial, fungal, rickettsial, viral, and parasitic agents and of vectors of such agents. It applies to all Center for Disease Control personnel and activities other than those related to the Clinical Laboratories Improvement Act. The latter will continue to distribute microbial agents and vectors in accordance with existing procedures.

Additional information on the distribution of cultures of microbial agents and of vectors is available from the Office of Biosafety.

II. POLICIES AND PROCEDURES

A. Distribution to High School and Undergraduate College Students

Effective immediately, the distribution of all cultures of microbial agents and of vectors of such agents by CDC personnel to high school and college undergraduate level students will be discontinued.*

The American Type Culture Collection, 12301 Parklawn Drive, Rockville, Maryland 20852, telephone 301-881-2600, maintains a variety of nonpathogenic bacterial, fungal, viral, and protozoal agents "approved" for distribution to and use by high school and college undergraduate students. Persons from either of these two groups may be advised to contact the ATCC directly for information on available cultures.

*This policy is not intended to interfere with or discourage worksite experience cooperative studies between CDC scientists and high school and college undergraduate level students. However, such studies will be conducted under the applicable provisions of Manual Guide - General Administration No. CDC-61, Worksite Experience Program.

II. POLICIES AND PROCEDURES (Continued)**A. Distribution to High School and Undergraduate College Students
(Continued)**

Dr. Ruth L. Russel, Chairman, Committee on Elementary and Secondary Education, Board of Education and Training, American Society of Microbiologists, will also provide advice and consultation on experimental design to elementary and secondary level students.

Dr. Russel's address is Microbiology Department, California State University, Long Beach, California 90840.

B. Distribution to Other Groups

Distribution of cultures of microbial agents and of vectors by CDC personnel to peer scientists, collaborators, participants in CDC training activities, and others shall be in accordance with the conditions described in the current edition of "Classification of Etiologic Agents on the Basis of Hazard." (A copy of this publication is available from the Office of Biosafety, CDC.)

The provisions of the Foreign Quarantine Regulations (42 CFR Section 71.156 of the PHS Regulations) regarding permits and of the Interstate Quarantine Regulations (42 CFR Section 72.25 of the PHS Regulations) regarding packaging and labeling are applicable as indicated. The cited conditions of distribution and the regulatory requirements apply to materials that are hand-carried as well as to materials that are mailed.

C. Records of Distributions

A record of each distribution of a culture of a microbial agent or of a vector shall be maintained by the employee initiating the distribution.

When applicable, Form CDC 3.616, Request for Shipment, will serve as a record of such distributions. This form is available from the CDC Warehouse and the Self-Service Store at the Clifton Road Facility.

In lieu of Form CDC 3.616, a memorandum or other written record containing the following information shall be maintained:

- Name, title, and organizational address of the person receiving the agent(s) or vector(s).
- Description of the agent(s) or vector(s) distributed and intended use of recipient(s).

Records of distribution of agents and vectors shall be maintained in accordance with B-356(16b) of the DHEW Records Management Manual -- "Dispose of after 10 years. Transfer to the Federal Records Center after 3 years." These records will be used to prepare reports or summaries as requested.

CENTRIFUGE SAFETY

- Section I. Introduction
II. Operating Instructions
III. Safety Precautions
IV. Postaccident Procedures

I. INTRODUCTION

This Guide provides standards for the use of centrifuges and procedures to be followed if a centrifuge accident occurs. Each employee using a centrifuge should become familiar with this information. Additional assistance is available upon request from the Office of Biosafety.

Each operator should be instructed on proper operating procedures before being allowed to use the instrument. Instructions should include balancing loads, using the proper head, and using accessory equipment.

Each employee who uses a centrifuge is responsible for the condition of the machine at the end of the procedure. This includes entering data in the log books, turning off the power, and cleaning up spills, broken glass, etc. Detailed records of operation should be made for most high speed centrifuges and rotors. The safe speed that rotors can be operated is determined by a rating formula which is based on numbers of starts and stops, r.p.m., total "G" loads, etc. Also, warranty coverage, service procedures, etc., for the machines are determined by hours of operation. These records should be kept in log books placed near each machine.

II. OPERATING INSTRUCTIONS

The lid should be closed when the centrifuge is in operation. If an unusual condition (such as a noise or vibration) begins, the centrifuge should be stopped immediately. On a zonal rotor, i.e., Ti-15, B-29, etc., excessive oscillations should be dampened when the seal assembly is stabilized by holding and/or repositioning the seal assembly in the shield support.

II. OPERATING INSTRUCTIONS (Continued)

An unbalanced load may cause the instrument to vibrate. The operator should check to be sure that heads are symmetrically loaded, tube caps are correctly seated, and swinging buckets are symmetrically placed. Particular attention should be given to verify that swing-out cups are supported correctly. The maximum speed rating for the rotor must not be exceeded.

The seal assembly of zonal rotors (Ti-15, B-29, for example) leaks and sprays fluid if excessive pressures are applied. Therefore, the operation of the instrument should begin at low pressures and then be slowly increased toward the manufacturer's recommended values.

III. SAFETY PRECAUTIONSA. Laboratory Area

Rooms where live etiologic agents are centrifuged should be identified with a warning sign "Caution--Biological Hazard--Infectious Agent--Do Not Enter Without Authorization From (Name and Telephone Number of Person in Charge of Lab)." These signs and frames are available from the Safety Office.

Use of this sign does not prohibit visitors from entering the room, but it advises them to inquire and determine if it is safe to enter. Signs can be removed between cycles if the shipment is used only rarely; however, if it is used frequently, visitors should always ask before entering.

Because of the hazards involved, continuous flow [includes batch type zonal rotors that require seal disconnection when operating (B-14 or B-15 rotor types)] centrifugation of live etiologic agents may be done only in installations approved by an official of the Office of Biosafety.

B. Tubes

Plastic centrifuge tubes should be carefully inspected prior to each ultra-centrifuge cycle. Only sound tubes should be used to process infectious material. Plastic tubes used in ultra-centrifuges are subjected to great pressure which sometimes cause them to break, especially after they have been through several cycles. Tubes likely to fail can often be identified by stress lines which appear in the area of junction of the sides and the bottom. Such tubes should be discarded.

III. SAFETY PRECAUTIONS (Continued)B. Tubes (Continued)

Tubes to be used in angle-head centrifuges must never be filled to the point that liquid is in contact with the lip of the tube when it is placed in the rotor, even though the meniscus will be vertical during rotation. When the tube lip is wetted, high G forces drive the liquid past the cap seal and over the outside of the tube.

Nitrocellulose tubes should be used only when "fresh" (clear, without discoloration, and flexible). Small lots should be ordered several times a year instead of one large lot once a year. Storage at 4° C. extends shelf life. Nitrocellulose tubes must not be used in angle-head centrifuges; instead, swinging bucket heads should be used. Autoclaving nitrocellulose tubes is dangerous and should be done only when no other method of decontamination is suitable. Then only a few tubes should be placed in one inch of water in a discard pan. Tubes in dry pans, old tubes, or tubes filling a pan are all dangerous as the tubes may explode when autoclaved. A safer method is to place used nitrocellulose tubes in a disinfecting solution known to be effective against the agent being processed.

C. Carrier Cups and Rotors

Accidents, such as tubes being broken, in any centrifuge have potential for producing large volumes of very finely divided aerosols. Therefore, safety carriers (carriers with individual screw caps which completely isolate each carrier cup) or rotors that are sealed shut should be used whenever infectious agents are centrifuged. After live etiologic agents are centrifuged, sealed rotors and safety cups should be opened only in a Biological Safety Cabinet.

The inside of the cups should be clean and smooth. Therefore, carrier cups of rotors need to be cleaned on a scheduled basis. They should be washed in warm, soapy water and scrubbed with a nylon brush. In some instances, fine steel wool should be used to remove stubborn deposits.

Cleanliness is the best preventive for rotor corrosion. Ultra-centrifuge heads, particularly, must be protected. After each use, the rotor should be rinsed in warm tap water and then with distilled water. If solid deposits persist, a mild detergent solution should be used with a stiff test tube brush. Then the detergent should be rinsed away with warm tap water and distilled water as before. Caustic solutions are particularly damaging and washing should be prompt.

II. SAFETY PRECAUTIONS (Continued)

C. Carrier Cups and Rotors (Continued)

When plastic tubes are used in dirty or rough cups, the tubes expand and sieze against the walls of the cups, making it very difficult to remove the tubes. In some instances, tubes have had to be pulled with pliers and have been torn or broken in removal. To avoid this possibility, the inside of the cups may be sprayed with a silicon aerosol spray or similar product. (See instructions that come with these ultra-centrifuges as rotors require special care which may differ from instructions in this Guide.)

D. Radioactive Materials

A radiation fume hood must be used in centrifugation operations involving the use of radioisotopes except in situations such as a radioimmuno-assay using very small quantities of isotopes. Specifications for fume hoods which are approved for radiological work may be obtained from the Radiation Safety Officer, CDC.

Incidents resulting in spills or dispersal of radioactive materials into the environment should be reported immediately to the Radiation Safety Officer.

Clean-up and decontamination of laboratory equipment for re-use are the responsibilities of the user. Disposal of radioactive-contaminated equipment and radioactive materials and waste products will be accomplished by the Radiation Safety Officer.

Information concerning the CDC license to use radioisotopes, AEC regulations, or other information regarding the use of radioisotopes may be obtained from the Office of Biosafety.

IV. POSTACCIDENT PROCEDURES

When the operator becomes aware that an accident has occurred, he should:

- Turn off the centrifuge.
- Warn others in the laboratory.
- Leave the room at once.
- Notify the chief of the laboratory.

The laboratory staff should not reenter the area or attempt cleanup if there are any doubts of the safety of this procedure.

IV. POSTACCIDENT PROCEDURES (Continued)

Generally, any good broad-spectrum germicide that does not damage centrifuge bowls or the rotors can be used for decontamination. One can be made by using a mixture of 20 per cent formalin solution in isopropanol, i.e., 20 parts of 40% formaldehyde solution and 80 parts isopropanol.

Depending on the agent being processed and other circumstances, the supervisor may need to contact the Office of Biosafety (which includes the Radiological Safety Officer) for assistance in decontamination and cleanup. Personnel of the Office of Biosafety have protective equipment which will allow them to work safely in contaminated environments. Their help should be requested whenever there is any question of safety.

Subpart CDC: 3-5.56

Procurement, Management, and Disposition of Controlled Drugs

PURPOSE

This Subpart sets forth responsibilities and procedures on the procurement, management, and disposition of controlled drugs at the Center for Disease Control.

DEFINITIONS

Controlled Drugs: Those items of narcotics and dangerous drugs identified by the Bureau of Narcotics and Dangerous Drugs (BNDD) in the regulations (Title 21, CFR, Food and Drugs Chapter II) implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970. The items are divided into five schedules (I, II, III, IV, and V), depending on the accepted medical use of the drug in the United States and the abuse potential. The BNDD publishes an inventory listing of the controlled drugs. A copy will be sent to CDC custodians by the registrants.

Registrant: The registrant is the person (at each separate location where controlled drugs are manufactured, distributed, or dispensed) who is officially registered with the BNDD. The Chief, Office of Biosafety, is the registrant for all CDC facilities in the Atlanta area. The chief of each CDC field station will designate the employee to be registered for that location. The facility receiver or custodian may also be the registrant.

Facility Receiver: The person designated in writing by the registrant at each facility to initially receive all controlled drugs and to distribute them to the appropriate custodians. The registrant or custodian may also be the facility receiver.

Custodian: The person designated in writing by the headquarters program/division director or the chief of the field station to be responsible for the requisitioning, storing, issuing, and recordkeeping of the controlled drugs in an individual laboratory or group of laboratories. The registrant or facility receiver may also be the custodian.

RESPONSIBILITIES AND PROCEDURES

<u>Responsibility</u>	<u>Action</u>
Director, CDC	1.1 Designate employee (registrant) to be registered for CDC headquarters and notify Contracts and Purchases Section, Administrative Services Branch, to coordinate application for new registration.
Chiefs of Field Stations	2.1 Designate employee (registrant) to be registered for that location (may be chief of field station), coordinate application for the registrant, and send the name and location of the registrant to the headquarters registrant (Chief, Office of Biosafety), the procurement office of the field station, and Administrative Services Branch.
Headquarters Program/ Division Directors and Chiefs of Field Stations	3.1 Designate in writing a custodian and an alternate for each individual laboratory (or group of laboratories) where controlled drugs will be stored and send a listing of the custodians and alternates and the building and room numbers of where the drugs will be stored to the registrant (if a field station registrant, send in duplicate one for the field station registrant to keep and one to forward to the headquarters registrant); to the facility receiver; to the Administrative Services Branch; and, if a field station, to the procurement office. Also, notify these officials of changes of custodians and alternates. 3.2 Designate in writing the persons in each individual laboratory who are authorized to use the controlled drugs and send a listing of these persons to the appropriate custodians. (Authority to make these designations may be redelegated to Branch or Section Chiefs.) 3.3 Indicate approval of requisitions for controlled drugs by signing the requisition (Form HSM 0.19 (CDC)).
All Registrants	4.1 Ensure that the facility complies with CDC rules and regulations governing controlled drugs. 4.2 Issue a power-of-attorney to appropriate officials of Contracts and Purchases Section, Administrative Services Branch, to procure Schedules I and II controlled drugs, if this is necessary.

RESPONSIBILITIES AND PROCEDURES (Continued)

<u>Responsibility</u>	<u>Action</u>
All Registrants (Continued)	<p>4.3 Designate in writing the individuals to be the facility receiver and alternate of controlled drugs. Notify the Administrative Services Branch; the appropriate custodians; and, if a field station, the procurement office of this designation.</p> <p>4.4 Provide custodians current lists of controlled drugs and inform them of responsibilities for maintaining the drugs, records, and inventories.</p>
Field Registrants	<p>5.1 Send to the headquarters registrant a listing of the field station custodians and alternate custodians and the building and room number where the drugs will be stored.</p> <p>5.2 Notify the headquarters registrant of the loss or disappearance of blank order forms and of inventories of surplus or unusable controlled drugs.</p> <p>5.3 Notify the headquarters registrant and the local police of theft (or suspected theft) or loss of controlled drugs.</p> <p>5.4 Each January, April, July, October, send to the headquarters registrant a copy of memorandums from all custodians at the field station reporting that the inventories have been completed, that the drugs on hand and records coincide or specify any overages/shortages. In January attach to the memorandum a copy of itemized inventory records for all custodians.</p>
Headquarters Registrant (Chief, Office of Biosafety)	<p>6.1 Serve as the liaison with BNDD for all CDC activities, including field stations, and provide field registrants with copies of BNDD lists of controlled drugs.</p> <p>6.2 Report immediately to the appropriate Regional Office of BNDD the loss or disappearance of blank order forms.</p>

RESPONSIBILITIES AND PROCEDURES (Continued)

<u>Responsibility</u>	<u>Action</u>
Headquarters Registrant (Chief, Office of Biosafety) (Continued)	<p>6.3 Upon notification of theft (or suspected theft) or loss of controlled drugs:</p> <ol style="list-style-type: none"> Notify the appropriate Regional Office of BNDD and also send BNDD Form 106 in accordance with Section 301.76 of the BNDD regulations. Notify local police if the theft or suspected theft is in the headquarters area. Notify the Chief, Property and Supply Management Section, Administrative Services Branch, to establish a board-of-survey to determine responsibility or liability. <p>6.4 Dispose of unwanted drugs by shipping via registered mail to the local office of BNDD. Send 4 copies of BNDD Form 41 with the drugs. (Excess and unwanted drugs may be transferred to other registered CDC laboratories. Therefore, the headquarters registrant will ascertain that disposal, rather than transfer, is indicated before disposal is begun).</p>
Administrative Services Branch (Contracts and Purchases Section)	<p>7.1 Pursuant to a power-of-attorney from each registrant (headquarters and field station), process all procurements for Schedules I and II controlled drugs, using BNDD Form 222c. Send copy 3 of completed BNDD order forms, along with pink, blue, and white tissue copies of SF-147, to the appropriate facility receiver (headquarters or field station).</p> <p>7.2 Using the headquarters registrant's BNDD number, order all headquarters procurements of Schedules III, IV, and V controlled drugs on SF-147, Order for Supplies or Services. Send pink, blue, and white tissue copies of the SF-147 to the facility receiver.</p> <p>7.3 Safeguard Department of Justice order blanks. As a minimum, store order blanks in a locked cabinet, preferably a combination lock type.</p>

RESPONSIBILITIES AND PROCEDURES (Continued)

<u>Responsibility</u>	<u>Action</u>
Administrative Services Branch (Contracts and Purchases Section) (Continued)	7.4 Report any loss or disappearance of the blank order forms immediately to the headquarters registrant (Chief, Office of Biosafety). 7.5 Coordinate application for headquarters registrations.
Administrative Services Branch (Property and Supply Management Section)	8.1 Determine need for board-of-survey in case of reported loss or theft (or suspected theft) of controlled drugs in accordance with Subparts 103-25.51 and 103-27.6302(b)(8) of the DHEW Materiel Management Manual. 8.2 By BNDD registration number, maintain a register of all controlled drugs acquisitions. (The register shall provide data to identify each requisition; organization and custodian of the drug; date received; description and quantity of the drugs.)
Field Station Procurement Office	9.1 Using the field station registrant's BNDD number, order all procurements of Schedules III, IV, and V controlled drugs for the field station on SF-147. Send the pink, blue, and white tissue copies of the SF-147 to the field station facility receiver.
Facility Receiver (or in his absence, the alternate facility receiver)	10.1 Receive the controlled drugs from the vendor or carrier. 10.2 Examine the drug containers before signing for receipt to ascertain whether the containers have been tampered with in transit. Notify the facility registrant if any containers are unacceptable or missing. 10.3 Enter on copy 3 of the BNDD order form (for Schedules I and II) and on the pink, blue, and white tissue copies of SF-147 (for all schedules of controlled drugs) the number of commercial or bulk containers of each item and the dates on which such containers are received.

RESPONSIBILITIES AND PROCEDURES (Continued)

<u>Responsibility</u>	<u>Action</u>
Facility Receiver (or in his absence, the alternate facility receiver) (Continued)	<p>10.4 Distribute the drugs to the appropriate custodian and obtain his signature and the building and room number where the drugs will be stored on copy 3 of the BNDD order form for Schedules I and II items and on the pink, blue, and white tissue copies of SF-147 for all Schedules. (Note: The facility receiver may also be the custodian and, in these instances, will sign the BNDD order forms and SF-147.)</p> <p>10.5 Forward the blue signed copy of SF-147 to Administrative Services Branch (Contracts and Purchases Section), pink signed copy of SF-147 to Financial Management Branch and retain the white tissue for files.</p> <p>10.6 By BNDD registration number and for each custodian maintain a current and accurate record of all controlled drugs ordered and distributed. (Note: This record must equal the total inventory record for all drugs received by all custodians of the facility.)</p>
Custodian (or in his absence, the alternate custodian)	<p>11.1 Use Form HSM 0.19 (CDC), Requisition for the Purchase of Services, Supplies and Equipment, to requisition all controlled drugs for his laboratory. Designate on the requisition the name and location of the facility receiver. (Form HSM 0.19 (CDC) is available from the CDC Warehouse and the Self-Service Store at the Clifton Road Facility.)</p> <p>11.2 Submit all requisitions through channels to the headquarters program/division director or field station chief for approval and forwarding to the appropriate procurement office, i.e.,</p> <p>a. Send all requisitions (headquarters and field stations) for all Schedules I and II items to Contracts and Purchases Section, Administrative Services Branch.</p> <p>b. Send all headquarters requisitions for Schedules III, IV, and V items to Contracts and Purchases Section.</p> <p>c. Send all field station requisitions for Schedules III, IV, and V items to the field station procurement office.</p>

RESPONSIBILITIES AND PROCEDURES (Continued)

<u>Responsibility</u>	<u>Action</u>
Custodian (or in his absence, the alternate custodian) (Continued)	<p>11.3 Accept delivery of the controlled drugs from the facility receiver.</p> <p>11.4 Examine the drugs, verifying the contents and quantities of each item before signing for receipt of them.</p> <p>11.5 Keep all controlled drugs and related records in a securely locked, substantially constructed cabinet.</p> <p>11.6 Ensure that the cabinets have no markings to indicate controlled drugs are stored therein.</p> <p>11.7 Maintain exclusive control of the keys to the cabinet. If a combination lock is used on the cabinet, limit the combination to the custodian and the alternate custodian.</p> <p>11.8 Keep records by BNDD registration number. This will separate records for Schedule I items from Schedules II, III, IV, and V items.</p> <p>11.9 Maintain a perpetual inventory record of each controlled drug on Form HSM 0.678 (CDC) (see Exhibit 1). (This form is available from the CDC Warehouse.) Indicate the BNDD registration number for the drug and the daily receipt and usage, including the amounts:</p> <ol style="list-style-type: none"> ordered on requisitions. received from the facility receiver. issued to each person in the laboratory for use at the bench or other work location. returned by each worker for storage in the locked cabinet. <p>11.10 Keep with the perpetual inventory record a listing of persons authorized to use the controlled drugs.</p>

RESPONSIBILITIES AND PROCEDURES (Continued)

<u>Responsibility</u>	<u>Action</u>
Custodian (or in his absence, the alternate custodian) (Continued)	<p>11.11 Prepare and maintain for at least two years a quarterly inventory record as follows:</p> <p>At the opening of business each first workday of January, April, July, and October:</p> <ol style="list-style-type: none"> Make a complete and accurate inventory of all stocks of controlled drugs. (Always make an exact count of Schedules I and II items. Make an exact count of Schedules III, IV, and V items unless the container is so graduated as to require an estimate count.) Reconcile quantities of the drugs on hand with the perpetual inventory record. Record the quarterly inventory on Form HSM 0.678 (CDC) (see item 5 in Exhibit 1). On April, July, October inventories, send a memorandum within three workdays to the registrant (in duplicate if a field station), reporting that the inventory has been completed and that the stock of drugs and records coincide or specify any overages or shortages. The quantity of drugs on hand is not required for this report. In January, prepare an itemized listing (by BNDD registration number) of all stocks of controlled drugs on hand. Attach the listing to a memorandum to the registrant reporting that the inventory has been completed and that the stock of drugs and records coincide or specify any overages or shortages. Immediately send a copy of the memorandum and listing to: <ol style="list-style-type: none"> (1) the registrant (if a field station, send two copies - one for the field station registrant to keep and another copy to send to the headquarters registrant). (2) the facility receiver. (3) the Chief, Property and Supply Management Section, Administrative Services Branch.

RESPONSIBILITIES AND PROCEDURES (Continued)

<u>Responsibility</u>	<u>Action</u>
Custodian (or in his absence, the alternate custodian) (Continued)	11.12 Make records available for inspection by duly authorized officials of CDC and BNDD.
	11.13 Report any surplus or unusable controlled drugs to the registrant for that facility.
	11.14 Report the loss or theft (or suspected theft) of controlled drugs to the registrant for that facility. (Note: Thefts must be reported whether the controlled drugs are subsequently recovered and/or the responsible parties are identified and action taken against them.)

Exhibit 1

1-102

HSM 0.678 (CDC)
2-73

- ① Record BNDD Registration Number.
- ② Enter date of requisition, record document number on requisition, record quantity ordered, file requisition in folder.
- ③ Enter date order was received, record document number on packing slip or invoice accompanying shipment, record quantity received and due in and balance of controlled drug on hand, and file all records in folder.
- ④ Enter date, quantity issued and balance on hand, and have recipient acknowledge receipt of drug by signing inventory record.
- ⑤ Enter date, record "quarterly inventory," post quantity on hand and sign. Also, report to registrant that inventory has been completed and that stocks and records coincide, or specify any shortages or overages. In January send itemized listing of drugs on hand with the report to the registrant.
- ⑥ Enter complete organization identification, building and room number where drugs are stored, and name of custodian of the drugs.
- ⑦ Enter complete information (see sample shown). Unit of issue must be the smallest quantity issued, i.e., tablet, ampule, ounce, etc.

CDC TN-73.1 5/10/73

SUBPART CDC: 3-5.5603

ETHYL ALCOHOL: Procurement, Usage, and Storage

PURPOSE

This Subpart defines policies and procedures on the procurement, usage, and storage of ethyl alcohol at all CDC facilities.

PROCUREMENT

Requisitions for ethyl alcohol must be approved by the bureau directors* or their designees in addition to the normal administrative approvals required for regular requisitions. Each requisition will be for ethyl alcohol only, containing no other items. In accordance with Procurement Subpart PHS: 3-5.56, the CDC installation will obtain the alcohol either from the PHS Supply Service Center or the Veterans Administration Supply Depot. Approval to obtain supplies of ethyl alcohol from other sources must be obtained from the Chief, Procurement and Materiel Management Office, who has been delegated authority to sign applications to procure tax-free and specially denatured alcohol (see Procurement Subpart CDC: 3-75.4).

USAGE

Ethyl alcohol should not be used for purposes where substitutes can be used; i.e., for disinfectant purposes, isopropanol or denatured alcohol should be used instead of ethyl alcohol.

STORAGE

Each laboratory will limit its supply of ethyl alcohol to the smallest amount consistent with the efficient, uninterrupted operation of its activities. Laboratories should be guided by the time required to receive the ethyl alcohol from the supplier.

Ethyl alcohol will be stored in locked cabinets. Supplies of ethyl alcohol and narcotics will not be stored together. All containers of ethyl alcohol will be kept in solvent storage cabinets approved by the National Fire Protection Association:

- If the containers are larger than half-gallon size.
- If the cumulative amount of flammable solvents stored in the room exceeds two gallons.

*References to bureau and bureau directors also apply to institute, clearinghouse, offices, and staff services and heads of these organizations, respectively.

Public Health Service
Center for Disease Control
Atlanta, Georgia 30333

July 3, 1969

CDC GENERAL MEMORANDUM NO. 69-11

LABELING OF EQUIPMENT SENT FOR MAINTENANCE/REPAIRS

To assure that all equipment sent to Engineering Services Division for maintenance and/or repairs is properly labeled as infectious, Form HSM 0-593 (CDC) must be affixed to the equipment. A copy of the self-adhesive form is illustrated on the reverse of this page.

If electronic or other specialized complex equipment must be decontaminated by extraordinary methods before repairs or maintenance can be performed, the CDC Biohazard Safety Office or the CDC Safety Office should be contacted.

Copies of Form HSM 0-593 (CDC) are available at each of the maintenance and repair shops or by telephone request to Engineering Services Division.

William C. Watson, Jr.
Executive Officer

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Center for Disease Control
Atlanta, Georgia 30333

July 3, 1969

December 28, 1970

ADDENDUM TO CDC GENERAL MEMORANDUM NO. 70-3

CDC GENERAL MEMORANDUM NO. 69-11

STORAGE OF EQUIPMENT, SUPPLIES, AND OTHER ITEMS IN BUILDING CORRIDORS AND ELEVATOR LOBBIES, CD

LABELING OF EQUIPMENT SENT FOR MAINTENANCE/REPAIRS

Since the issuance of CDC General Memorandum No. 70-3, certain items of

equipment, some of the
These obstructions, fire, explosion, and other hazardous situations.
To assure that all equipment sent to Engineering Services Division for maintenance and/or repairs is free from hazardous infectious organisms, Form HSM 0.593 (CDC) must be signed and affixed to the equipment. A copy of the self-adhesive form is illustrated on the reverse of this page.

It has been determined that if electronic or other specialized complex equipment must be decontaminated by extraordinary methods before repairs or maintenance can be performed, the CDC Biohazards Control Officer or the CDC Safety Office should be contacted.

As acknowledged, copies of Form HSM 0.593 (CDC) are available at each of the maintenance and repair shops or by telephone request to Engineering Services Division. These items were placed in corridor and elevator lobby areas without proper authority and will be removed upon completion of scheduled building renovations and/or space assignments. Unless specifically authorized in writing, no additional equipment will be placed in CDC building corridor or elevator lobby areas.

William C. Watson, Jr.
Executive Officer

In certain areas (e.g., north and south corridors of Buildings 4 and 5, at the Clifton Road Facility), enclosed shelving which does not extend into corridor areas beyond building columns has been installed. Warehouse storage facilities may remain and similar ones may be installed in other areas provided authorization is obtained prior to their installation. In addition, uniform transfer racks, utilized by the Laboratory Division's Laundry Activity to distribute laboratory apparel, will continue to be placed in corridor areas. Insofar as possible these racks will be placed in areas that do not obstruct passage ways.

Effective immediately, it will be necessary for any activity which has material, equipment, furniture, carts or supplies located in building corridor or elevatory lobby areas (other I-107 the north and south corridors of Buildings 4 and 5), to justify and obtain approval for the placement of such items. If adequate justification does not exist, they should be removed immediately.

July 3, 1969

This equipment has not been contaminated
with dangerous chemicals or etiologic agents
and, without being decontaminated, may be
safely serviced, repaired, disassembled, or
reissued.

To assure that all equipment sent to Engineering Services Division
for maintenance and/or repair is free from hazardous infectious
organisms, Form HSM 0.593 (CDC) must be signed and affixed to the
equipment. A copy of the self-adhesive form is illustrated on the
reverse of this page.

Name _____
Title _____

If electronic or other specialized complex equipment must be decon-
taminated by extraordinary methods, repairs or maintenance
can be performed, the CDC Biosafety Control Officer or the CDC
Safety Office should be contacted.

This equipment was decontaminated with

Copies of Form HSM 0.593 (CDC) are available at each of the main-
tenance and repair shops or by telephone request to Engineering
Services Division.

on _____ 19 ____.

William C. Watson, Jr.
Executive Officer

Office of Biosafety

HSM 0.593 (CDC)
REV. 4-73

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Center for Disease Control
Atlanta, Georgia 30333

December 28, 1970

ADDENDUM TO CDC GENERAL MEMORANDUM NO. 70-3

STORAGE OF EQUIPMENT, SUPPLIES, AND MATERIALS IN CORRIDOR AND ELEVATOR LOBBIES, CDC FACILITIES

Since the issuance of CDC General Memorandum No. 70-3, certain items of equipment, furniture, supplies, and/or materials are again being placed in some of the corridor and elevator lobby areas of various CDC facilities. These obstructions to passageways can create serious hazards in case of fire, explosion, loss of lights due to fire or explosion, or other emergency situations.

It has been, and continues to be, a standing policy of CDC that all building corridors and elevator lobbies will be kept clear of all extraneous materials including laboratory equipment, supplies, carts, furniture, and general storage items.

As acknowledged in CDC General Memorandum No. 70-3, there are some items of laboratory equipment such as freezers and refrigerators already located in restricted areas. Most of these items were placed in corridor and elevator lobby areas without proper authority and will be removed upon completion of scheduled building renovations and/or new space assignments. Unless specifically authorized in writing, no additional equipment will be placed in CDC building corridor or elevator lobby areas.

In certain areas (e.g., north and south corridors of Buildings 4 and 5, at the Clifton Road Facility), enclosed shelving which does not extend into corridor areas beyond building columns has been installed. These storage facilities may remain and similar ones may be installed in other areas provided authorization is obtained prior to their installation. In addition, uniform transfer racks, utilized by the Laboratory Division's Laundry Activity to distribute laboratory apparel, will continue to be placed in corridor areas. Insofar as possible these racks will be placed in areas that do not obstruct passage ways.

Effective immediately, it will be necessary for any activity which has material, equipment, furniture, carts or supplies located in building corridor or elevatory lobby areas (other than the north and south corridors of Buildings 4 and 5), to justify and obtain approval for the placement of such items. If adequate justification does not exist, they should be removed immediately.

The procedures for obtaining approval for allowing items to remain in the corridor and/or lobby areas are as follows:

A. Preliminary Request

The initiating activity will submit an oral request, through channels, to the program/division director, office or staff service chief. If the request is approved, it should then be formalized.

B. Formal Request

1. The requesting activity will:

a. initiate a memorandum (in duplicate) to the Chief, Real Property and Communications Management Section, Administrative Services Branch, explaining:

- the specific need to locate the materials and/or equipment in the corridor or lobby areas
- why such materials cannot be located in laboratory or office areas

- what action has been taken to assure that laboratory or office space is not being utilized by other items of equipment, furniture, etc., that could be used to accommodate the item for which the approval is requested

b. forward the request through organizational channels.

2. Higher organizational levels of the originating activity will:

a. properly endorse the request

b. forward it through channels to the Chief, Real Property and Communications Management Section.

3. The Chief, Real Property and Communications Management Section will:

a. conduct a review of the request, in collaboration with the CDC Safety Officer and the CDC Biological Hazards Control Officer, to determine the feasibility of the request

b. indicate the action taken on the original copy of the request and return it through channels to the requesting activity.

James D. Bloom
Acting Executive Officer

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : All Personnel Using Animals at
Clifton Road Facility, Building E

DATE: March 30, 1971

FROM : Director, Office of Biosafety

SUBJECT: NO SMOKING in Animal Quarters

1. The recent fire in a waste receptacle in the animal quarters emphasizes the need to prohibit smoking in these areas.
2. Animals in some of the rooms have been inoculated with infectious agents. Prudent biosafety measures forbid placing anything in one's mouth--cigarettes, cigars, pipes, or fingers--while in the animal quarters.
3. Refuse in the animal quarters is almost all flammable and is stored in disposable paper bags (flammable). Fire in these rooms may go undetected for some time and is likely to asphyxiate animals on test.
4. Dr. Quist has instructed his staff not to smoke in the animal quarters and has posted NO SMOKING signs. You are also requested not to smoke in areas so posted. Your cooperation will be appreciated.

Robert H. Huffaker, D.V.M.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
Center for Disease Control

TO : All CDC Laboratory Personnel
in the Atlanta Area

DATE: October 25, 1972

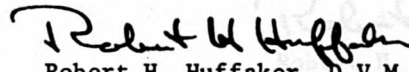
FROM : Director, Office of Biosafety and
Acting Safety Officer

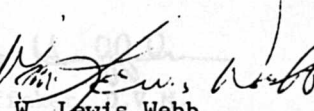
SUBJECT: Use of Chemical Fume Hoods During Non-Duty Hours

On October 28, 1971, we sent a memorandum to warn you not to use fume hoods after working hours or on weekends because the air supply to the buildings is off at these times. A few days ago, several large beakers containing a mixture that included ethyl ether were left overnight in a Biological Safety Cabinet to evaporate. It is now appropriate to re-issue the memorandum.

Air from chemical fume hoods goes into the building air exhaust system, and the hoods do not function unless the building air system is operating. The building air systems are turned off at night, during weekends, and holidays; therefore, fume hoods cannot be used during these time periods.

If an emergency situation exists that requires the use of fume hood, the building air supply and exhaust can be turned on during non-duty periods. Arrangements must be made in advance with Engineering Services Branch, extension 3214.


Robert H. Huffaker, D.V.M.
Director
Office of Biosafety


W. Lewis Webb
Acting Safety Officer

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
Center for Disease Control

TO : All CDC Laboratory Personnel

DATE: November 8, 1972

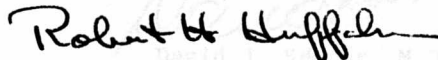
FROM : Biohazards Control Officer

SUBJECT: Cannulas

The hypodermic needle has long been recognized as being one of the most hazardous tools used in microbiological laboratories. They are used in CDC laboratories for many purposes besides inoculating animals; for transferring, diluting, mixing, and so on. In many of these uses the needles need not be sharp, and the use of blunt needles (cannulas) would reduce the risk of accidental inoculation of laboratory personnel. In addition to being safer, cannulas are less expensive than sharp hypodermic needles.

Mr. Homer E. Pinson, Chief, Laboratory Service Unit, Technical Services Section, Laboratory Division, now has cannulas in several sizes and lengths ready for issue.

Personnel in each laboratory that uses hypodermic needles are encouraged to consider the use of cannulas wherever possible.



Robert H. Huffaker, D.V.M.

Enclosure

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
Center for Disease Control

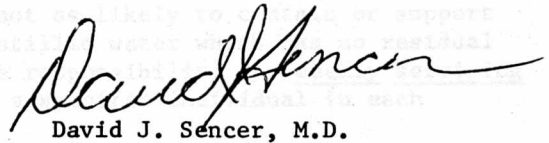
TO : All Supervisors and Employees

DATE: November 17, 1972

FROM : Director, CDC of Biotechnology

SUBJECT: Visitors in Laboratory Areas

1. Supervisors are reminded that they are responsible for the safety of employees and visitors in their laboratories and work areas. Enforcement of rules to prevent exposure of children (see attached memo) or non-immunized persons to etiologic agents or other hazards depends on the participation of first-line supervisors.
2. Your active support and cooperation in this matter are expected and will be appreciated.



David J. Sencer, M.D.
Assistant Surgeon General

Enclosure

DISTRIBUTION: All CDC laboratory employees in
Laboratory Division, Epidemiology Program,
Ecological Investigations Program, and
Biology Program

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
Center for Disease Control

TO : All CDC Laboratory Employees

DATE: June 6, 1973

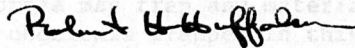
FROM : Chief, Office of Biosafety

SUBJECT: Eye Wash Bottles and Eye Protection

There are several brands of plastic eye wash bottles available for emergency use in laboratories. The user fills them with water and places them in a holder near the work bench. Should harmful material be splashed in someone's eye, the eye cup on the bottle is held against the face and the bottle squeezed to wash the eye.

We have cultured the water in a number of the bottles and found them to be contaminated with bacteria—including Pseudomonas spp. The use of water colonized with bacteria to wash corneal and conjunctival tissues traumatized or irritated by chemicals may result in infection.

For this reason, it is recommended that all eye wash bottles be rinsed and refilled with tap water once a week. Tap water is preferred as it contains residual chlorine and is not as likely to contain or support pathogen growth as deionized or distilled water which has no residual chlorine. It is suggested that the responsibility for weekly servicing of eye wash bottles be assigned to a specific individual in each laboratory.



Robert H. Huffaker, D.V.M.

DISTRIBUTION: All CDC laboratory employees in
Laboratory Division, Epidemiology Program,
Ecological Investigations Program, and
Malaria Program

I-119


Robert H. Huffaker, D.V.M.

I-121

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
Center for Disease Control

TO : All Laboratory Workers, CDC

DATE: June 15, 1973

FROM : Chief, Office of Biosafety

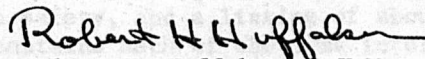
SUBJECT: Caustic Chemicals and Eye Protection

Within the last 4 months, three accidents have been reported at CDC in which acid was splashed on the faces of laboratory personnel. In each case there were burns near the eyes but, fortunately, there was no eye damage. In none of these instances were the people wearing safety glasses or other protective equipment.

While it will never be possible to remove all hazards inherent in work with caustic and other dangerous chemicals, there are reasonable and practical safety precautions that can and must be taken to reduce risk. Important among these is the wearing of safety glasses with side shields, goggles, or face masks, depending on the hazard. Eye protection equipment is available without cost from the Safety Office and must be worn whenever dangerous or caustic chemicals are handled. Responsibility for procurement of eye protection equipment rests with laboratory supervisors. They will also have to determine when this equipment must be worn; in some laboratories eye protection should be worn at all times by everyone, including visitors. Consultation on eye protection is available from the Safety Office.

Contact lenses do not provide eye protection. The capillary space between the contact lenses and the cornea may trap any material present on the surface of the eye. Caustic chemicals trapped in this space cannot be washed off the surface of the cornea. If the material in the eye is painful or the contact lens is displaced, muscle spasms will make it very difficult, if not impossible, to remove the lens. For this reason, contact lenses must not be worn by persons exposed to caustic chemicals unless goggles and/or plastic face masks are also worn to provide full protection. It is the responsibility of supervisors to identify employees who wear contact lenses.

It is suggested that supplies of caustic chemicals, i.e., ammonia solution, liquid phenol, acids, strong bases, etc., be stored no higher than counter-top level to minimize the possibility of facial and upper body burns in the event of spills or breakage of containers. It is also a good practice to use the smallest sized container compatible with the need.


Robert H. Huffaker, D.V.M.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE

Center for Disease Control

TO : CDC Laboratory Supervisors

DATE: July 25, 1973

FROM : Chief, Office of Biosafety

SUBJECT: Chemical Hazards

The systematic reporting of laboratory accidents provides a twofold benefit: It provides data from which epidemiologic assessments can be made and establishes a basis for employee injury compensation. Evaluation of accident reports provides a basis for developing and implementing corrective procedures and practices to prevent recurrence of accidents.

Following a review of a number of accidents in CDC, it was apparent that laboratorians, including chemists, are not always aware of all the hazards involved when using chemicals. It is suggested that before a new employee is introduced to a procedure, or before a new procedure is introduced to an employee, the following be done:

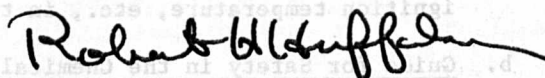
- a. The supervisor list the compounds to be used (or produced) in the reaction; and that each of these be checked in a chemical reference for hazardous properties.
- b. The hazardous chemicals, kinds of hazards, and appropriate protective and first aid measures be discussed in detail with everyone in the laboratory who has a need to know.

We will be happy to share our references on laboratory safety. At the present time we have:

- a. Laboratory Waste Disposal Manual by Manufacturing Chemical Association, 2nd edition. This contains allowable TLV, hazard ratings by health, fire, and reactivity, flash points, ignition temperature, etc., in tabular form for 1121 chemicals.
- b. Guide for Safety in the Chemical Laboratory by Manufacturing Chemical Association, 2nd edition. This is a good general reference on chemical laboratory safety and contains reference (a) in its entirety. It also has a good section on incompatibilities.
- c. Dangerous Properties of Industrial Material by Irving Sax, 3rd edition. This book has sections on general laboratory safety, air handling, radiation safety, and a listing of about 13,000 chemicals. This list contains much of the same information as

(a) and, in addition, has more details on hazards by routes of exposure, etc.

- d. Clinical Toxicology of Commercial Products by Gleason, et al. 3rd edition. This reference has a short section on hazards of specific chemicals and a long, detailed section on brand name products likely to be involved in accidental poisonings. It is used primarily in poison centers and other clinical situations. A current, detailed card index system of many brand name products is also on hand.
- e. Handbook of Laboratory Safety by Chemical Rubber Company, 2nd edition. Much like (c), having a long section on general laboratory safety and a short section listing 1094 chemicals in tabulation form as in (a).
- f. Toxic Substances List by HEW, NIOSH. 1972 edition. A long list of chemicals (13,000+) each with a very brief computer printout of known toxicity, by animal species.
- g. Handbook of Poisoning, 6th edition, by Dreisbach. Contains good description of toxicity, clinical findings, and treatment of poisoning for most of items commonly involved in poisonings. Most useful in a clinical setting, such as a poison control center, but helpful in evaluating potential hazard of a chemical.
- h. The Care, Handling, and Disposal of Dangerous Chemicals, 1970, by Gaston. A paperback of interesting information on all kinds of chemicals. Not much depth and not very well organized. Lists some incompatibilities, etc.
- i. The Merck Index, 8th edition. Much like (c) except that it also lists many chemicals that are not toxic. Hazards are given as well as medical uses, etc. A good reference.



Robert H. Huffaker, D.V.M.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : All CDC Laboratory Personnel

DATE: March 13, 1974

FROM : Director, Office of Biosafety

SUBJECT: Disposal of Infectious or Toxic Laboratory Wastes
A Policy Statement

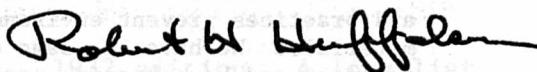
1. In order to be good neighbors, we must be able to assure the communities in which our laboratory facilities are located that our policies, procedures, and practices prevent environmental contamination with infectious and toxic materials. We have the same obligation to prevent exposure of maintenance, service, and housekeeping personnel to infectious and toxic materials in the course of their work.
2. Except as otherwise provided, all laboratory specimens or materials consisting of, containing, or contaminated with blood, plasma, serum, urine, feces, or other human or animal tissues or fluids, as well as inoculated media, cultures, and other potentially infectious materials must be either incinerated or sterilized by autoclaving or by use of a chemical sterilant (in cases where autoclaving or incineration is not possible) approved by the Office of Biosafety before disposal.
3. When there is no reasonable evidence to indicate that clinical specimens or other materials may contain an infectious agent, discard into the sanitary sewer without sterilization may be permitted. Materials that may be discarded directly into the sanitary sewer include:
 - a. Uninoculated liquid mediums, tissue cultures, and nutrient fluids
 - b. Serum, plasma, or blood (provided that the specimens are not believed to contain any etiologic agent that might not otherwise enter the sanitary sewer system). See paragraph 4 regarding disposal of specimen containers.
4. All glassware, pipettes, slides, etc., used in the examination or testing of biological materials must be autoclaved or chemically disinfected before being discarded or prepared for reuse. Single-use bottles, tubes, vials, and other biological specimen containers should not be placed in wastebaskets customarily emptied by janitorial personnel.

Delicate and expensive calibrated chemical laboratory glassware which is not contaminated with biological materials need not be sterilized prior to return to the glassware preparation area. Caustic, corrosive, or toxic materials must be removed from glassware and similar items by washing or neutralization before such glassware is taken from the laboratory.

5. Lids on discard pans containing material to be autoclaved should be marked with autoclave tape (*). All pans must be identified with a sticker (*) that shows the laboratory of origin. In addition, pans containing non-contaminated chemical glassware should be marked with a special sticker (*) to indicate that autoclaving is not required.

6. Detailed instructions on loading pans (don't mix disposable and non-disposable ware, no knives or needles in with reusable glassware, etc.) are available from the glassware kitchen that serves each facility.

7. Detailed instructions regarding wastes that contain radioactive materials are available from the person holding the AEC license at each facility. Arrangements have been made for safe, legal disposal of these wastes at each location, and these procedures must be carefully followed.



Robert H. Huffaker, D.V.M.

(*) These can be provided by arrangement with the Office of Biosafety.

EYE PROTECTION

- Section I. Introduction
II. Equipment
III. Special Hazards
IV. Eye-Hazard Areas
V. Supervisor's Responsibilities

I. INTRODUCTION

This Guide defines eye-hazard areas where wearing eye-protective equipment is mandatory. It also sets forth the supervisor's responsibilities, both in identifying locations where possible damage to the eyes could occur and in enforcing precautionary procedures in these areas.

II. EQUIPMENT

The Occupational Safety and Health Act of 1970 and good safety practices dictate that "Protective eye and face equipment shall be required where there is a reasonable probability of injury that can be prevented by such equipment...suitable eye protectors shall be provided where machines or operations present the hazard of flying objects, glare, liquids, injurious radiation, or a combination of these factors."

The type of eye protection required depends on the hazard. For most situations, safety glasses with side shields are adequate. Where there is danger of splashing chemicals, special goggles are required. For more hazardous operations, a face shield or a combination face shield and safety goggles or glasses (some of which may be supplied with prescription lenses) should be used. (See Exhibit I for examples.) Failure to wear the prescribed eye-protection equipment will be grounds for disciplinary action. The Office of Biosafety will assist in the choice of suitable protective equipment and will provide protective eye and face equipment. CDC field stations may purchase this equipment locally or request it from the Office of Biosafety.

III. SPECIAL HAZARDS

Contact lenses do not provide eye protection. The capillary space between the contact lenses and the cornea may trap material present on the surface of the eye. Chemicals trapped in this space cannot be washed off the surface of the cornea. If the material in the eye is

III. SPECIAL HAZARDS (Continued)

painful or the contact lens is displaced, muscle spasms will make it very difficult to remove the lens. Therefore, contact lenses must not be worn by persons exposed to hazardous chemicals unless goggles and/or plastic face masks are also worn to provide full protection. It is the responsibility of supervisors to identify employees who wear contact lenses.

Supplies of caustic chemicals, i.e., ammonia solution, liquid phenol, acids, strong bases, etc., should be stored no higher than countertop level to minimize the possibility of facial and upper body burns in the event of spills or breakage of containers. It is also a good practice to use the smallest size container compatible with the need.

Emergency eye-wash facilities should be available in areas where corrosive or caustic materials are handled.

IV. EYE-HAZARD AREAS

Eye-protective equipment must be worn in areas posted as "Eye-Hazard Areas." These areas include where:

- Corrosive or caustic materials are handled.
- Explosive materials are handled.
- Hollow glassware is under vacuum or pressure.
- Cryogenic materials are handled.
- Flying particles may be generated (grinders, mills, power saws, drill presses, lathes, etc.).
- Molten metal is used or metal is melted (soldering, leading joints, etc.).
- Gas or electric arc welding is done.
- Processes can produce aerosols of infectious agents (removing lyophil vials from liquid nitrogen, etc.).

Help for supervisors in identifying "Eye-Hazard Areas" is available from the safety officer at each CDC installation. Signs (Exhibit II) are available from the Office of Biosafety and from CDC field station safety officers.

V. SUPERVISOR'S RESPONSIBILITIES

The supervisor is responsible for:

- Determining that an eye hazard exists.
- Placarding the work area.
- Determining the type of eye protection equipment needed; obtaining necessary assistance from the Office of Biosafety and/or the CDC field station safety officers.
- Ensuring that the equipment is available to employees.
- Ensuring that the necessary protective equipment is worn by employees.

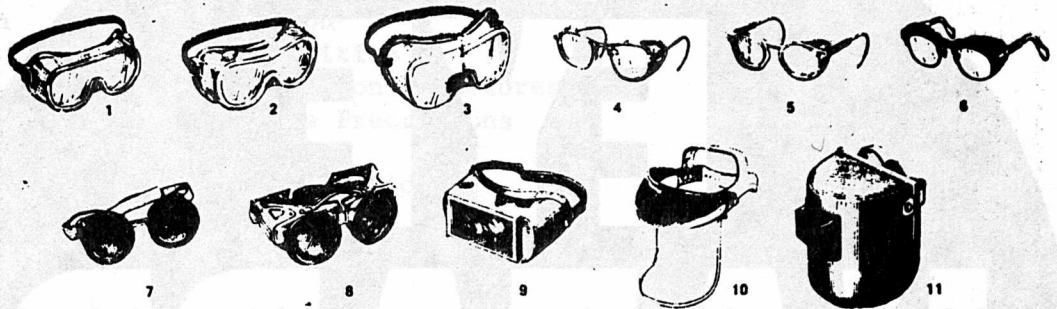
Failure of the supervisor to enforce eye-protective requirements will be grounds for disciplinary action.

APPLICATIONS		
OPERATION	HAZARD	RECOMMENDED PROTECTION
ACETYLENE CUTTING ACETYLENE WELDING	SPARKS, HOT METAL, FLYING PARTICLES	1, 2, 3
CHEMICAL WELDING	SPARKS, HOT METAL, FLYING PARTICLES	2, 3, 4, 5, 6, 7, 8, 9, 10
CHIPPING	FLYING PARTICLES	1, 2, 3, 4, 5, 7, 8, 9
ELECTRIC ARC WELDING	SPARKS, INTENSE HEAT, HOT METAL	2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100
FURNACE OPERATIONS	GLARE, HEAT, HOT METAL	2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100
GRINDING - LIGHT	FLYING PARTICLES	1, 2, 3, 4, 5, 6, 7, 8, 9, 10
GRINDING - HEAVY	FLYING PARTICLES	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100
LABORATORY	CHEMICAL SPILLS, GLASS BREAKAGE	2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100
MACHINING	FLYING PARTICLES	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100
MOLDED METALS	HEAT, GLARE, SPARKS, SPLASH	2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100
SPOT WELDING	FLYING PARTICLES, SPARKS	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100

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Selection Chart

Recommended Eye and Face Protectors for Use in Industry, Schools, and Colleges



1. GOGGLES, Flexible Fitting, Regular Ventilation
 2. GOGGLES, Flexible Fitting, Hooded Ventilation
 3. GOGGLES, Cushioned Fitting, Rigid Body
 *4. SPECTACLES, Metal Frame, with Sideshields
 *5. SPECTACLES, Plastic Frame, with Sideshields
 *6. SPECTACLES, Metal-Plastic Frame, with Sideshields

- ** 7. WELDING GOGGLES, Eyecup Type, Tinted Lenses (Illustrated)
 7A. CHIPPING GOGGLES, Eyecup Type, Clear Safety Lenses (Not Illustrated)
 ** 8. WELDING GOGGLES, Coverspec Type Tinted Lenses (Illustrated)
 8A. CHIPPING GOGGLES, Coverspec Type, Clear Safety Lenses (Not Illustrated)
 ** 9. WELDING GOGGLES, Coverspec Type, Tinted Plate Lens
 10. FACE SHIELD (Available with Plastic or Mesh Window)
 **11. WELDING HELMETS

*Non-sideshield spectacles are available for limited hazard use requiring only frontal protection.
 **See appendix chart "Selection of Shade Numbers for Welding Filters."

APPLICATIONS		
OPERATION	HAZARDS	RECOMMENDED PROTECTORS: Bold Type Numbers Signify Preferred Protection
ACETYLENE—BURNING ACETYLENE—CUTTING ACETYLENE—WELDING	SPARKS, HARMFUL RAYS, MOLTEN METAL, FLYING PARTICLES	7, 8, 9
CHEMICAL HANDLING	SPLASH, ACID BURNS, FUMES	2, 10 (For severe exposure add 10 over 2)
CHIPPING	FLYING PARTICLES	1, 3, 4, 5, 6, 7A, 8A
ELECTRIC (ARC) WELDING	SPARKS, INTENSE RAYS, MOLTEN METAL	9, 11 (11 in combination with 4, 5, 6, in tinted lenses, advisable)
FURNACE OPERATIONS	GLARE, HEAT, MOLTEN METAL	7, 8, 9 (For severe exposure add 10)
GRINDING—LIGHT	FLYING PARTICLES	1, 3, 4, 5, 6, 10
GRINDING—HEAVY	FLYING PARTICLES	1, 3, 7A, 8A (For severe exposure add 10)
LABORATORY	CHEMICAL SPLASH, GLASS BREAKAGE	2 (10 when in combination with 4, 5, 6)
MACHINING	FLYING PARTICLES	1, 3, 4, 5, 6, 10
MOLTEN METALS	HEAT, GLARE, SPARKS, SPLASH	7, 8 (10 in combination with 4, 5, 6, in tinted lenses)
SPOT WELDING	FLYING PARTICLES, SPARKS	1, 3, 4, 5, 6, 10

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**EYE
HAZARD
AREA**

**EYE PROTECTION
MUST BE WORN!**

AREA SUPERVISOR

DECONTAMINATION OF LABORATORY SINK DRAINS TO REMOVE AZIDE SALTS

- Section
- I. Introduction
 - II. Responsibilities
 - III. Decontamination Procedures
 - IV. Maintenance Precautions
 - V. Warning Signs
 - VI. General Precautions

I. INTRODUCTION

Lead sink drains and traps are common in CDC laboratories. Sodium azide, which is used in a number of laboratory procedures, readily reacts with lead, copper, or brass to form metallic salts. These salts are sensitive to heat, friction, and concussion. Lead azide, for example, is a more sensitive primary explosive than nitroglycerine and is a more efficient detonating agent than mercury fulminate. Explosions in contaminated systems may be initiated by heating with a torch to remove or repair traps and drains, by friction from metal "snakes" used to open clogged drains, or by concussion from hammers, chisels, and wrenches.

All laboratory sink traps and drains which have not been converted to polyvinyl chloride (PVC) are potentially contaminated. Therefore, they must be chemically treated prior to any maintenance, to remove the salts (usually lead azide).

II. RESPONSIBILITIES

Office of Biosafety

The Office of Biosafety is responsible for providing assistance in assuring that the proper decontamination procedure has been followed prior to any maintenance on a non-PVC laboratory drain.

Engineering Services Office

Engineering Services Office personnel are primarily responsible for ascertaining that drains have been decontaminated. Prior to beginning work, the Engineering Services Office supervisor will confirm with the supervisor of the laboratory that the drain has been properly decontaminated.

Laboratory Supervisors

The supervisor of the laboratory is responsible for the decontamination of the sink requiring maintenance services.

II. RESPONSIBILITIES (Continued)**Laboratory Supervisors (Continued)**

NOTE: In CDC facilities other than those in the Atlanta area, the laboratory supervisor and maintenance personnel are jointly responsible for insuring that the sink has been decontaminated. However, the Office of Biosafety will provide necessary assistance.

III. DECONTAMINATION PROCEDURES

- Prepare 1 - 2 liters of 10% w/v sodium hydroxide (100 g NaOH per liter of water).
- Syphon all liquid from the trap and drain using a soft rubber or plastic hose. Use proper precautions against any hazardous chemicals which may be present.
- Pour the sodium hydroxide slowly into the trap.
- Tape a Chemical Hazard warning sign (available from the Office of Biosafety) to the sink. Write "Do Not Use Sink" on the sign.
- Allow the solution to remain in the trap a minimum of 16 hours.
- Flush the drain with water for a minimum of 15 minutes. If the drain will not flow, the sodium hydroxide should be removed by syphoning, if possible, then diluted with water. Engineering Services Office personnel or other maintenance personnel outside the Atlanta area should be advised that the drain contains caustic material.

IV. MAINTENANCE PRECAUTIONS

Because the possibility of residual sodium hydroxide will always exist, personnel should wear rubber gloves and face shields when breaking the drain line or trap for maintenance. (This equipment should be worn when breaking any laboratory drain, as the presence of hazardous chemicals should always be suspected.)

V. WARNING SIGNS

The Office of Biosafety will provide appropriate warning signs to be attached to all laboratory sink drains and traps made of materials other than plastic. However, the absence of a warning sign

V. WARNING SIGNS (Continued)

on a sink with a metal drain does not mean that the above procedure is unnecessary. All such sinks must be decontaminated prior to maintenance.

VI. GENERAL PRECAUTIONS

Formation of metallic azides can be minimized by preventing collection of sodium azide solutions in traps and drains. This can be done by thoroughly flushing drains with water when discarding any solutions containing sodium azide.

PREFACE

Section II of this manual is the result of contributions from many of the professional staff of the Center for Disease Control (CDC). It was prepared by or under the direction of the Medical Advisory Committee to the Director, CDC. Grateful acknowledgement is made to James O. Mason, M.D., who served as Chairman of the Committee and provided guidance during many of the stages in the preparation of Section II, and to members of the subcommittee who were directly responsible for its development:

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Parasitology Section, Microbiology Branch, Laboratory
Robert E. Kishine, D.V.M., Chief, Virology Section, Microbiology
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George F. Mallory, M.D., Chief, Bacteriology Section, Microbiology
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Myron G. Schultz, M.D., D.V.M., Chief, Epidemiology Program
Peter R. Smith, Ph.D., Chief, Bacteriology Section, Microbiology Branch, Laboratory
Fred R. Young, M.D., Chief, Epidemiology Program

In addition, the following individuals have contributed to this section: Philip S. Gruchman, M.D., Chief, Bacteriology Section, Microbiology Branch, Laboratory; Hermann, M.D.; Roslyn Q. Robinson, M.D.; and Fred R. Young, M.D.

Appreciation is also expressed to the following individuals for their assistance in the preparation of this section:

R. Bruce Dill, M.D.,
Assistant Director
for Program, and
Chairman, Medical Advisory
Committee to Center Director

This manual is for information only and does not constitute
endorsement by the Public Health Service or the U.S. Department
of Health, Education, and Welfare.

SECTION II

MICROBIOLOGIC AGENTS WITH HAZARDOUS FOR PERSONS WORKING OF BIOSECURITY PREVENTIVE ASPECTS

Use of trade names is for identification only and does not constitute endorsement by the Public Health Service or by the U.S. Department of Health, Education, and Welfare.

SECTION II

Preface

PREFACE

Section II of this manual is the result of contributions from many of the professional staff of the Center for Disease Control (CDC). It was prepared by or under the direction of the Medical Advisory Committee to the Director, CDC. Grateful acknowledgement is made to James O. Mason, M.D., who served as Chairman of the Committee and provided guidance during many of the stages in the preparation of Section II, and to members of the subcommittee who were directly responsible for its development:

- John V. Bennett, M.D., Chairman of the subcommittee and Chief,
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- Fred E. Tosh, M.D., Deputy Director, Ecological Investigations
Program.

In addition, the following individuals made substantial contributions to the vaccine section: Philip S. Brachman, M.D.; Eugene J. Gangarosa, M.D.; Kenneth L. Herrmann, M.D.; Roslyn Q. Robinson, Ph.D.; R. Keith Sikes, D.V.M.; and Lowell S. Young, M.D.

Appreciation is also expressed to the innumerable additional persons who assisted in the preparation of Section II.

H. Bruce Dull, M.D.,
Assistant Director
for Program, and
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TABLE OF CONTENTS

SECTION II

Preface	
Introduction	vii
Operational Requirements for Safe Laboratory Handling of Hazardous Micro-organisms	
Introduction	3
Table 1: Index to Operational Requirements	4
Table 2: Operational Requirements for Safe Laboratory Handling of Hazardous Micro-organisms	6
Explanation of Column Headings in Table 2	7
Vaccines and Indications for Use in Laboratory Workers Dealing with Hazardous Microbiologic Agents	
Introduction	11
Anthrax Vaccine	13
BCG Vaccine	16
Botulium Toxoid, Pentavalent (ABCDE)	19
Cholera Vaccine	21
Diphtheria and Tetanus Toxoids	23
Eastern Equine Encephalitis (EEE) Vaccine	26
Immune Serum Globulin for Protection Against Viral Hepatitis	28
Influenza Vaccine	32
Measles Vaccine	34
Plague Vaccine	36
Poliomyelitis Vaccine	38
Q Fever Vaccine	40
Rabies Vaccine	42
Rabies Exposure in Laboratories—A Statement on Safety	45
Rocky Mountain Spotted Fever (RMSF) Vaccine	46
Rubella Vaccine	48
Russian Spring Summer Encephalitis (RSSE) Vaccine	51
Smallpox Vaccine	53
Tetanus Toxoid (see “Diphtheria and Tetanus Toxoids”)	56
Tularemia Vaccine	57
Typhoid Vaccine	60
Typhus Fever (Epidemic) Vaccine	62
Venezuelan Equine Encephalitis (VEE) Vaccine	64
Yellow Fever (YF) Vaccine	65
General — Vaccination During Pregnancy	69

INTRODUCTION

The Medical Advisory Board to the Director, Center for Disease Control (CDC), has given the name "biosecurity" to the Center's broad program of preventive medicine, which is particularly designed to protect the health of those associated with biological laboratories. The program includes general health care, proper management of biological emergencies, and safe laboratory practices. The laboratory and immunization aspects of biosecurity for hazardous microbiologic agents are presented in this manual. The principles and practices described in this manual are recommended to reduce the risk of laboratory-acquired infections among laboratory workers, their supporting staffs, other employees, and the people who live in communities where laboratory facilities are located.

The prompt and proper identification and reporting of hazards and accidents is essential to an effective biosecurity program. These responsibilities rest mainly with laboratory supervisors. In general, when a problem arises, the employee must notify his supervisor immediately. The supervisor determines whether to request assistance from others such as the Biohazards Control or Safety officers. Supervisors are also responsible for the safety of visitors. They must determine that visitors are properly immunized, understand inherent risks, and need to be in potentially hazardous or restricted areas and that they have received appropriate instructions in safety.

Implementation of an effective biosecurity program depends upon participants' having the necessary knowledge to carry out the program. An employee who is aware of risks is less likely to be exposed. The same is true if he has been trained in safe laboratory procedures. Everyone who works in a biological laboratory should have a sense of responsibility for safety and access to knowledge of safe laboratory procedures. He must know how to protect himself, as well as those with whom he comes in direct or indirect contact.

INTRODUCTION

This section provides certain safety requirements for handling specific hazardous micro-organisms. These requirements derive from judgment based on present knowledge; as further knowledge accumulates and additional vaccines are developed, the requirements for some agents will change. The operational requirements are also based, in part, on the existing facilities and resources at CDC. Similar precautions probably would not be feasible in many other institutions. Information on required vaccines appears on pages II-11 through II-64.

In the following tables on operational requirements for handling hazardous micro-organisms, no attempt was made to cover all microbiologic agents. Agents that are not listed, however, can be handled safely in the laboratory without special equipment, techniques, or immunization.

Precautions are indicated only for those agents that are known to be associated with an infection hazard. Optional or debatable items have been excluded; only those items deemed essential for the safe handling of the agent are included. A table of operational requirements for handling hazardous micro-organisms is highly desirable in all laboratories to ensure the safe handling of these agents. The absence of negative air pressure in laboratories working with certain agents is not associated with an infection hazard.

Several additional operational principles and practices are recommended for laboratories even though they may not be required for safety with all micro-organisms. As a general principle, doors to laboratories should be kept closed. Entrances and exits, and visits by extraneous personnel, should be minimized. Drinking, or smoking in the laboratory is undesirable. Handwashing by laboratory personnel should be encouraged, and bulb pipetting, a good laboratory procedure, can be generally recommended. Disinfection of work surfaces after working with a disease agent is strongly recommended as a routine measure. All of these general recommendations are desirable, even if they are not specifically needed for the safe handling of certain agents.

The following index table (Table 1) lists hazardous micro-organisms within the basic categories of Bacteria, Parasites, Viruses (including Rickettsia and Bedsonia), and Fungi. Each agent has been given a number and an alphabetic letter that identifies its "Precaution Category" (PC). The letter appears immediately to the right of the name of the agent. Table 2, the operational requirements table, contains precaution categories in alphabetic order; the specific requirements for handling a particular agent are indicated by "+" entries under the various columns. Micro-organisms that require the same set of precautions are grouped within the same precaution category and, to conserve space, are identified by their code numbers.

Comments on each column heading in Table 2 follow the table.

INTRODUCTION

This section presents certain safety requirements for handling specific hazardous micro-organisms. These requirements derive from judgment based on present knowledge; as further knowledge accumulates and additional vaccines are developed, the requirements for some agents will change. The operational requirements are also based, in part, on the existing facilities and resources at CDC. Similar precautions probably would not be feasible in many other institutions. Information on required vaccines appears on pages II-11 through II-64.

In the following tables on operational requirements for safety in the laboratory, no attempt was made to cover all microbiologic agents. All known micro-organisms that are not listed, however, can be handled safely in the laboratory without special equipment, techniques, or immunization of personnel.

Precautions are indicated only when they are clearly required for the safety of laboratory workers or others. Optional or debatable items have been excluded; only those items deemed absolutely necessary for safety are presented. Thus, the following table of operational requirements presents only minimal safety criteria. For example, it is highly desirable that all laboratories be under negative air pressure; however, the absence of negative air pressure in laboratories working with certain agents may not be associated with an infection hazard.

Several additional operational principles and habits might be routine in laboratories even though they may not be required for safety with all micro-organisms. As a general principle, doors to laboratories should be kept closed except for necessary entrances and exits, and visits by extraneous persons should be discouraged. Eating, drinking, or smoking in the laboratory is undesirable. Handwashing by laboratory personnel should be encouraged, and bulb pipetting, a good laboratory procedure, can be generally recommended. Disinfection of work surfaces after working with a disease agent is strongly recommended as a routine measure. All of these general recommendations are desirable, even if they are not specifically needed for the safe handling of certain agents.

The following index table (Table 1) lists hazardous micro-organisms within the basic categories of Bacteria, Parasites, Viruses (including Rickettsia and Bedsonia), and Fungi. Each agent has been given a number and an alphabetic letter that identifies its "Precaution Category" (PC). The letter appears immediately to the right of the name of the agent. Table 2, the operational requirements table, contains precaution categories in alphabetic order; the specific requirements for handling a particular agent are indicated by "+" entries under the various columns. Micro-organisms that require the same set of precautions are grouped within the same precaution category and, to conserve space, are identified by their code numbers.

Comments on each column heading in Table 2 follow the table.

Table 1

INDEX TO OPERATIONAL REQUIREMENTS

OID**	BACTERIA	PC***	OID**	BACTERIA	PC***
1	Actinobacillus-all species (except <i>A. mallei</i>)	D	23	Mycobacteria-all other species	D
2	<i>Actinobacillus mallei</i>	BB	24	Mycoplasma-all species	D
3	Antinomycetes-all species	D	25	<i>Neisseria gonorrhoeae</i> and <i>N. meningitidis</i>	D
4	<i>Aeromonas salmonicida</i>	D	26	<i>Pasteurella pestis</i> ,* <i>tularensis</i> ,* <i>multocida</i> * (Type B)	AA
5	<i>Arizona arizonae</i> -all serotypes	D	27	<i>Pasteurella</i> -all other species	D
6	<i>Bacillus anthracis</i> *	AA	28	<i>Pseudomonas pseudomallei</i>	BB
7	Bartonella-all species	N	29	<i>Salmonella typhi</i> *	G
8	Bordetella-all species	D	30	Salmonella-all other species	D
9	Brucella-all species	BB	31	Shigella-all species	D
10	<i>Clostridium botulinum</i> *	AA	32	<i>Sphaerophorus necrophorus</i>	D
11	<i>Clostridium tetani</i> *	G	33	<i>Staphylococcus aureus</i>	D
12	Clostridia-other species	D	34	<i>Streptobacillus moniliformis</i>	D
13	<i>Corynebacterium diphtheriae</i> *	G	35	<i>Streptococcus pneumoniae</i>	D
14	Corynebacteria-other species	A	36	<i>Streptococcus agalactiae</i> <i>S. equi</i> , <i>S. equisimilis</i> <i>S. pyogenes</i> of Lancefield's Groups A, B, C, G	D
15	<i>Erysipelothrix insidiosa</i>	D	37	<i>Treponema pallidum</i> , <i>pertenue</i> , <i>carateum</i>	D
16	<i>Haemophilus ducreyi</i> , <i>H. gallinarum</i> <i>H. influenzae</i>	D	38	<i>Vibrio comma</i> *	K
17	<i>Herellea vaginicola</i>	A	39	<i>Vibrio fetus</i>	D
18	Klebsiella-all species	A	40	<i>Yersinia enterocolitica</i>	D
19	Leptospira-all species	D			
20	Listeria-all species	D			
21	<i>Mima polymorpha</i>	A			
22	<i>Mycobacterium avium</i> , <i>bovis</i> , <i>johnnei</i> , <i>tuberculosis</i>	CC			
<hr/>					
OID**	PARASITES	PC***	OID**	PARASITES	PC***
41	<i>Echinococcus granulosus</i>	C	52	<i>Pneumocystis carinii</i>	T
42	<i>Echinococcus multilocularis</i>	C	53	<i>Shistosoma haematobium</i>	H
43	<i>Leishmania braziliensis</i>	N	54	<i>Shistosoma japonicum</i>	H
44	<i>Leishmania donovani</i>	N	55	<i>Shistosoma mansoni</i>	H
45	<i>Leishmania mexicana</i>	N	56	<i>Taenia solium</i>	B
46	<i>Leishmania tropica</i>	N	57	<i>Toxoplasma gondii</i>	T
47	<i>Naegleria gruberi</i>	L	58	<i>Trypanosoma cruzi</i>	N
48	<i>Plasmodium falciparum</i>	F	59	<i>Trypanosoma gambiense</i>	D
49	<i>Plasmodium malariae</i>	F	60	<i>Trypanosoma rangeli</i>	B
50	<i>Plasmodium ovale</i>	F	61	<i>Trypanosoma rhodesiense</i>	D
51	<i>Plasmodium vivax</i>	F			

OID**	VIRUSES, RICKETTSIA, BEDSONIA	PC***	OID**	VIRUSES, RICKETTSIA, BEDSONIA	PC***
62	Adenoviruses-all types	I	85	<i>Rabies-Street virus</i> *	S
63	Arboviruses-general	Y	86	Reoviruses	I
64	B. virus	CC	87	Respiratory syncytial virus	J
65	Coxsackie A & B-all types	J	88	Rhinovirus	I
66	Cytomegalovirus	I	89	<i>Rickettsia rickettsii</i> *	DD
67	Echoviruses-all types	I	90	<i>Rubella</i> *	K
68	Encephalomyocarditis virus	L	91	Simian viruses, (except B virus and Marburg)	J
69	Hepatitis-infectious & serum	I	92	<i>Smallpox virus</i> <i>Major and Minor</i> *	DD
70	Herpesviruses except B	L	93	Tacaribe group viruses except Tamiami	EE
71	Infectious bronchitis- like virus	L	94	Tamiami virus	L
72	<i>Influenza virus-all types</i> *	I	95	Tick-borne viral enceph- litis: (<i>Russian-Spring- Summer-Encephalitis</i> * and all other viruses of complex except Langat)	X
73	K virus	P	96	<i>Vaccinia</i> *	P
74	Langat	R	97	Varicella	J
75	Lassa virus	EE	98	Venezuelan encephalitis virus-exotic strains	Y
76	Marburg virus	EE	99	VEE-domestic and vaccine strains	W
77	<i>Measles virus</i> *	K	100	Vesicular stomatis & other rhabdoviruses	V
78	Murine viruses, including ectromelia, LCM, murine hepatitis, etc.	E	101	<i>Yellow Fever</i> *	X
79	<i>Mumps virus</i> *	K			
80	Newcastle Disease virus	I			
81	<i>Polioviruses</i> *	M			
82	Psittacosis, LGV	U			
83	<i>Q Fever</i> , * <i>R. prowazeki</i> *, and all other rickettsia except <i>R. rickettsii</i>	Z			
84	Rabies-Fixed & attenuated	I			

OID**	FUNGI	PC***
102	<i>Blastomyces dermatididis</i>	O
103	<i>Cryptococcus neoformans</i>	O
104	<i>Paracoccidioides</i>	O
105	<i>Histoplasma capsulatum</i>	Q
106	<i>Coccidioides immitis</i>	Q
107	<i>Sporothrix schenckii</i>	O

*Vaccines for these agents are described
on pages II-13 through II-64.

**OID = Organism Identification Number

***PC = Precaution Category

Table 2¹

OPERATIONAL REQUIREMENTS FOR SAFE LABORATORY HANDLING OF HAZARDOUS MICRO-ORGANISMS

Precaution Category	Geographic Isolation	Controlled Access	Negative Air Pressure	Hoods and Cabinets	Disinfection			Bulb Pipetting Required	Special Protective Equipment			Special Precautions with Work Involving		Special Aerosol Precautions (Centrifuge, Blender, etc)	Immunization Available and Required	Organisms Requiring These Precautions
					Work Sur-faces	Entire Work Area	Material Before Leaving Work Area		Gloves	Masks	Other Special Clothing or Guards	Insects	Animals			
A					+											14,17,18,21
B								+								56,60
C													+			41,42
D					+			+								1,3,4,5,8,12,15,16,19,20,23,24,25,27,30,31,32,33,34,35,36,37,39,40,59,61
E							+	+								78
F												+	+			48,49,50,51
G					+			+							+	11,13,29
H					+			+	+				+			53,54,55
I					+		+	+								62,66,67,69,72,80,84,86,88
J				+	+		+	+								65,87,91,97
K					+		+	+							+	38,77,79,90
L				+	+		+	+						+		47,68,70,71,94
M				+	+		+	+							+	81
N				+	+			+				+	+			7,43,44,45,46,58
O		+		+	+		+	+						+		102,103,104,107
P				+	+		+	+						+	+	73,96
Q		+	+	+	+		+	+						+		105,106
R				+	+		+	+				+	+	+		74
S					+		+	+	+				+		+	85
T	+	+		+	+			+	+				+	+		52,57
U	+	+	+	+	+		+	+						+		82
V	+			+	+		+	+				+	+	+		100
W			+	+	+		+	+				+	+	+		99
X	+	+	+	+	+		+	+				+	+	+	+	95,101
Y	+	+	+	+	+	+	+	+	+			+	+	+	+	63,98
Z	+	+	+	+	+	+	+	+		+	+	+	+	+	+	83
AA	+	+	+	+	+	+	+	+	+	+		+	+	+	+	6,10,26
BB	+	+	+	+	+	+	+	+	+	+		+	+	+		2,9,28
CC	+	+	+	+	+	+	+	+	+	+	+	+	+	+		22,64
DD	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	89,92
EE	+	+	+	+	+	+	+	+	+	+	+	+	+	+		Newly discovered agents and 75,76,93

1. An explanation of column headings follows this table.

EXPLANATION OF COLUMN HEADINGS IN TABLE 2

Column 1: **Precaution Category** – The explanation is given on page II– 6 .

Column 2: **Geographic Isolation** – The action of isolating in a separate room or building in which no other work is concurrently conducted. A ventilating system to the room that prevents recirculation of air is implied. Exhaust air may be passed through High Efficiency Particulate Air (HEPA) filters or incinerated. For extremely hazardous agents, an air lock should also be used.

Column 3: **Controlled Access** – The exclusion of extraneous persons from areas where certain agents are being handled. Such control decreases the probability of distractions resulting in accidents and limits the number of exposed individuals should an accident occur.

The degree to which access is limited depends upon the risk associated with being in the area: the greater the hazard, the more restrictive the entrance requirements.

Corridors are the least hazardous of any locations in restricted laboratory areas. Areas in which the work is associated with a greater degree of risk are marked by signs reading "Caution, do not enter without current immunization against (name of disease)" or "Caution, infectious agents, do not enter without authorization from (name of investigator)." These signs are posted only while the risk is present.

Entrance to some areas should be restricted to the staff assigned to it. Access to areas in which very hazardous agents are being used should be controlled with locks and keys. No-access areas should be posted with signs reading "Warning: Highly Infectious Material: *Keep Out*." In temporary situations, such as following an accident, a large sign with bright red printing reading "Danger: DO NOT ENTER: Contaminated Areas" is posted. Areas posted with either of these signs are off limits to *all* personnel except the investigator who posted the sign. One should not pass these signs for *any* reason, not even to fight fire.

Questions about the location of areas of restricted access, the hazards in the areas and the risk of infection, the times when restricted areas can be visited, or the immunizations required for access should be directed to the Biohazards Control Officer.

Column 4: **Negative Air Pressure** – Ideally, the air pressure in all laboratories should be negative in relation to the pressure in surrounding corridors, thus helping to prevent agents from leaving the work area. When negative pressure is required, as shown in Table 2, it is essential for safety. Even when cultures are manipulated under hoods, negative pressure in the general lab area in relation to that in surrounding corridors is still highly desirable. In addition, doors to all laboratories should be closed except for necessary entrances and exits.

Column 5: **Hood and Cabinets** – These include protected work areas such as the CDC Bio-Safety Cabinet, glove boxes, laminar flow safety cabinets, and gastight isolators.

Column 6: **Disinfections** — Standard methods suitable for disinfection of work surfaces, entire work area, and material before leaving work area have not been presented. Disinfection should routinely take place when work with agents is completed, and each laboratory should be cleaned, work surfaces decontaminated, and all contaminated material either covered in discard pans or autoclaved at the end of the work day. The Biohazards Control Officer should be contacted for specific instructions.

Column 7: **Bulb Pipetting** — This heading is self-explanatory.

Column 8: **Protective Equipment** —

Gloves, including gloves on cabinet or hood ports, should be worn whenever one is handling organisms which call for this precaution. Gloves prevent the direct invasion of micro-organisms through intact skin and greatly reduce the hazards of indirect spread.

Masks should be worn to protect against the aerosol spread of certain organisms. Such masks should be worn except when the work is done in: a) a sealed cabinet in rooms with isolated ventilation systems with exhaust control, or b) effective immunizing agents have been given to all who might be exposed. High efficiency, disposable surgical masks are recommended; they are capable of reducing by 2 logs the number of airborne micro-organisms that are inhaled. Special respirators or supplied air equipment may have essentially complete respiratory protection.

Other Special Clothing or Guards — Face masks or shields, caps, safety gloves, booties, or even complete changes of clothing may be indicated for aerosol work with certain very hazardous agents. No attempt has been made to specify which special equipment may be needed for which special agents. The Biohazards Control Officer should be consulted for advice and guidance.

Column 9: **Special Precautions with Work Involving Insects and Animals** — These precautions have been stipulated for hazardous agents that might be capable of spread to humans through insects and animal vectors. Containment facilities should be secure before work is begun. The excretions and secretions of infected animals and insects may be infectious to humans, and personnel who must come in contact with them should routinely use special protective equipment. In some instances, discharges are capable of establishing disease in nature. These wastes must be decontaminated before they are released from the facility.

Column 10: **Special Aerosol Precautions** — Centrifuges, blenders, and other equipment capable of creating aerosols should be operated in separate "isolation" rooms or hoods. Special care should be taken in loading centrifuges to avoid accidental breakage during operation. Safety equipment to prevent the formation of aerosols is available and should be used. The Biohazards Control Officer should be consulted for further information.

Column 11: **Immunization Available and Required** — Immunization is generally recommended for all diseases against which effective, safe, and licensed vaccines have been developed. However, there are no vaccines against many highly virulent organisms, and some vaccines for such agents are investigational and without clear documentation of efficacy in humans. Nonetheless, in certain circumstances, the seriousness of the disease and the absence of other effective therapy may dictate their use.

INTRODUCTION

This part of Section II contains detailed information on vaccines for each of the 20 agents for which immunization was required in the preceding subsection. It also includes descriptions of BCG and the influenza vaccines, although these were not required. Specific indications for use in laboratory workers have been based on the nature of the exposure to these microbiologic agents.

Special immunization requirements for individuals working with certain agents. Employees responsible for initiating action to assure the required immunizations administer each of the 20 required vaccines.

made through the CDC clinic. The CDC Biohazards Control Office oversees the immunization of persons at risk.

The copy of the vaccine status, license status, and efficacy of the vaccine for use of the laboratory workers that should receive the vaccine are presented along with the vaccine and laboratory and precautions.

References on vaccine reactions follows.

Vaccines and Indications for use in Laboratory Workers Dealing with Hazardous Microbiologic Agents

1. Description

1.1 Composition

INTRODUCTION

This part of Section II contains detailed information on vaccines for each of the 20 agents for which immunization was required in the preceding subsection. It also includes descriptions of BCG and the influenza vaccines, although these were not required. Specific indications for use in laboratory workers have been based on the nature of the anticipated exposure to these microbiologic agents.

Special immunizations may be a condition of employment for individuals working in certain areas or with certain agents. Employee supervisors are responsible for initiating action to assure that employees receive the required immunizations. Arrangements to administer each of the 20 required vaccines can be

Anthrax vaccine (Anthrax Protective Antigen, Aluminum Hydroxide Adjuvanted) consists of a filtrate factor readily (from the bacterial cells elaborated during anaerobic growth of an virulent nonencapsulated strain of *Bacillus anthracis* in a chemically defined medium with aluminum hydroxide gel as an adsorbent, formalin as a stabilizer, and benzalkonium chloride as a preservative. Quantitative com- minimum formalin.

made through the CDC clinic. The CDC Biohazards Control Officer oversees the immunization of persons at risk.

The composition of each vaccine, its licensure status, storage requirements, supplier, reactions, and efficacy are given. General recommendations for use of the vaccine and the specific laboratory workers that should receive the vaccine are presented along with information on dose, immunity, and laboratory problems. Finally, contraindications and precautions in using each vaccine are given.

A short bibliography of selected references on vaccine efficacy, laboratory accidents, and reactions follows the above information on each vaccine.

Section, prepared by aerobic cultures local and some erythema 1 to 2 cm. in diameter, with minimal local tenderness, and occasional pruritus at the inoculation site. This type of reaction would not have been noted except that each vaccine was examined at 24 and 48 hours after vaccination. Both the mild and the moderate local reactions were noted within 24 hours and generally disappeared within 24 to 48 hours. A few vaccines developed small, firm, painless nodules at the injection site. These persisted for several weeks. There was no correlation between the development of local reactions and successive inoculations. Approximately 0.1% developed more significant local reactions—edema, erythema, and pruritus involving the upper arm—and systemic fever and malaise. The few who developed this type of reaction responded to antihistamines within 24 hours. Since the initial evaluation, the new preparation prepared under aerobic or anaerobic conditions has been used in over 10,000 inoculations. No difference in degree of reactivity has been noted.

Before release, each batch of vaccine is potency-tested in laboratory animals (rabbits) for equivalence with standards established by Wright and colleagues. The human evaluation studies CDC conducted among susceptible employees in a goat hair processing mill revealed the effectiveness to be 92.5%, with a lower 95% confidence limit of 65%.

Recommended primarily for persons who work with *B. anthracis* in the laboratory or with materials known to be or very likely to be contaminated with *B. anthracis*. Within the laboratory, persons who work directly with the organism and

2. Recommendations

2.1 General

ANTHRAX VACCINE

1. Description

1.1 Composition

Anthrax vaccine (Anthrax Protective Antigen, Aluminum Hydroxide Adsorbed) consists of a filtrate factor readily separable from the bacterial cells elaborated during anaerobic growth of an avirulent nonencapsulated strain of *Bacillus anthracis* in a chemically defined medium with aluminum hydroxide gel as an adsorbent, formalin as a stabilizer, and benzethonium chloride as a preservative. Quantitative composition of the drug includes aluminum, 0.17%; aluminum oxide, 0.32%; benzethonium chloride, 1/40,000; and formalin, 0.009%.

1.2 Licence

Licensed.

1.3 Storage

Refrigerate. Vaccine is dated for use within a certain number of years after production.

1.4 Supplier

Immunobiologics Activity, Biological Reagents Section, Laboratory Division, CDC.

1.5 Reactions

Adverse reactions are not a significant problem. The initial evaluation using the vaccine prepared by aerobic cultures revealed that 2.8% of the vaccinees developed moderate local reactions consisting of erythema, induration, edema, and some tenderness. About 30% developed a small ring of erythema 1 to 2 cm. in diameter, with minimal local tenderness, and occasional pruritis at the inoculation site. This type of reaction would not have been noted except that each vaccinee was examined at 24 and 48 hours after vaccination. Both the mild and the moderate local reactions were noted within 24 hours and generally disappeared within 24 to 48 hours. A few vaccinees developed small, firm, painless nodules at the injection site. These persisted for several weeks. There was no correlation between the development of local reactions and successive inoculations. Approximately 0.1% developed more significant local reactions—edema, erythema, and pruritis involving the upper arm—and systemic fever and malaise. The few who developed this type of reaction responded to antihistamines within 24 hours. Since the initial evaluation, the new preparation prepared under aerobic or anaerobic conditions has been used in over 10,000 inoculations. No difference in degree of reactivity has been noted.

1.6 Efficacy

Before release, each batch of vaccine is potency-tested in laboratory animals (rabbits) for conformance with standards established by Wright and colleagues. The human evaluation studies CDC conducted among susceptible employees in a goat hair processing mill revealed the effectiveness to be 92.5%, with a lower 95% confidence limit of 65%.

2. Recommendations

2.1 General

Recommended primarily for persons who work with *B. anthracis* in the laboratory or with materials known to be or very likely to be contaminated with *B. anthracis*. Within the laboratory, persons who work directly with the organism and

those who take care of animals exposed to the organism either by inoculation or by the aerosol route should also be immunized. Persons who work in the same laboratory but not with *B. anthracis* should be immunized because of the possibility of accidental contact with the organism. All equipment in the laboratory in which *B. anthracis* is handled should be disinfected before it leaves the lab. Such disinfection should be mandatory. If such disinfection is practiced, personnel handling the glassware from the laboratories need not be immunized. If glassware is not so disinfected, persons handling these contaminated materials should also be immunized. Nonimmunized persons should not be allowed in the laboratory in which *B. anthracis* is being handled.

Employees in textile mills where imported, raw goat hair is processed should be immunized. The vaccine may also be used among employees who handle imported, contaminated wool, especially that from areas where anthrax is endemic among sheep. In industrial plants where less than 5% of surface swabs are positive for *B. anthracis*, the risk of employees developing anthrax is slight; therefore a mass immunization program is probably not indicated. Such immunization programs are advised where the contamination rate is in excess of 5%.

Veterinarians who are likely to come in contact with *B. anthracis*-infected animals or carcasses should be immunized.

2.2 Dose

Primary: 0.5 ml. subcutaneously at 2-week intervals for 3 doses.

Booster: 0.5 ml. subcutaneously at 6 months and then annually. Individuals who show moderate local reactions to the vaccine have been given 0.1 ml./1:100 dilution of the vaccine without subsequent reactions.

2.3 Immunity

There is no good way to assess an individual's immunity or susceptibility to the disease; however, persons who have had cutaneous anthrax and those with histories of primary immunizations and the requisite booster inoculations are considered immune.

2.4 Laboratory Problems

No laboratory-acquired cases of anthrax have occurred at CDC. However, 26 cases occurred at Fort Detrick during 1944-46, after which there were only five others. Five cases have been reported from other laboratories.

3. Contraindications

Precautions

There are no known contraindications or precautions in using the vaccine. In persons who have had the natural disease, moderate local reactions may follow a single inadvertent inoculation of the vaccine. They should not be vaccinated.

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Elaboration of the Protective Antigen of *Bacillus anthracis* in Chemically Defined Media. J. Bacteriol. 68(4):474-482, October 1954.

3. Wright, G.G., Green, T.W., and Kanode, R.G., Jr. Studies on Immunity in Anthrax. V. Immunizing Activity of Alum-Precipitated Protective Antigen. J. Immunol. 73(6):387-391, December 1954.

BCG VACCINE

1. Description

1.1 Composition BCG vaccine is an attenuated live bacterial vaccine. (The initials stand for the bovine tubercle *bacillus* originally isolated by Nocard in 1902 and attenuated by *Calmette* and *Guerin* by repeated passages on a potato medium to which ox bile was added.) attenuation was begun in 1908; in 1920, after more than 200 passages, the bacillus was declared incapable of producing fatal tuberculosis in cattle, monkeys, guinea pigs, and rabbits. For composition and production details, see Rosenthal's book listed in bibliography.

1.2 License Licensed in the United States.

1.3 Storage Fresh liquid vaccine deteriorates on storage; use within 14 days of manufacture. Loses viability rapidly at warm temperatures (30°C.) and when exposed to sunlight.

The capacity of freeze-dried vaccine to produce satisfactory tuberculin sensitivity may be retained for long periods, but it is sensitive to heat, although less so than liquid vaccine, and should normally be stored in a refrigerator.

1.4 Supplier Research Foundation, University of Illinois (Rosenthal vaccine); Eli Lilly and Company (Glaxo vaccine).

1.5 Reactions Safety of the vaccine has been attested by extensive and prolonged use; however, adverse reactions do occur. Unduly large vaccination lesions and subcutaneous abscesses are not infrequent and are influenced by dose and technique. The local complication most often reported is adenitis of the regional lymph nodes. It occurs most frequently in infants. Frequency is related to dose. Dermatologic complications are rare and seem to be more severe and frequent among persons who have been revaccinated. Systemic complications of BCG are uncommon. Disseminated infection and death have been reported, but are rare.

1.6 Efficacy BCG vaccination does not necessarily prevent infection with virulent tubercle bacilli, but it is generally agreed that it prevents disastrous complications of primary infection with virulent tubercle bacilli (especially miliary tuberculosis and tuberculous meningitis).

The extent to which BCG vaccine may enhance naturally acquired protection associated with low-grade tuberculin sensitivity is of particular relevance. In trials covering a wide variety of social and epidemiologic circumstances in which the protective effect of the vaccine has been defined by a close follow-up of a vaccinated and control group, BCG has conferred a substantial and similar degree of protection (about 80%). However, a much smaller degree of protection (about 30%) has been found in trials by the U.S. Public Health Service (PHS) in communities known to contain a large proportion of persons with naturally acquired low-grade tuberculin sensitivity.

An adequately performed BCG vaccination undoubtedly provides fairly satisfactory protection against (a) the immediate consequences of a tuberculous infection, (b) serious forms of primary tuberculosis, and (c) early postprimary pulmonary tuberculosis. The protection against late postprimary types of tuberculosis seems to be slighter and more uncertain.

2. Recommendations

2.1 General

The following statement (made in 1966) on the use of BCG vaccination in the United States represents the position of both the American Thoracic Society and the U.S. PHS.

RECOMMENDED USAGE

For the individual: Since modern methods for detection, isolation, treatment, and chemoprophylaxis, when adequately applied, are highly successful in controlling tuberculosis, BCG should be reserved for situations in which these methods cannot be applied. BCG should be used for the uninfected person or small groups of uninfected people living in unavoidable contact with one or more uncontrolled infectious persons who cannot or will not obtain or accept supervised treatment.

For groups: Based on available data, there is no epidemiologic indication for the use of BCG on a group or community basis in the United States. In particular, BCG is not recommended for medical and paramedical personnel and students or for employees and inmates of penal and mental institutions, because the knowledge of tuberculin conversion, if it occurs, is essential to instituting chemoprophylaxis and identifying and treating the infectious source. Moreover, adequate tuberculosis control programs can be developed in such groups with reasonable assurance of cooperation.

A so-called "micro-epidemic" of infection is another situation in which BCG is not recommended. Today, with low rates of transmission and expanded tuberculin testing, such outbreaks will be more easily recognized than in the past. Their management requires the prompt identification and removal of the source of infection and the identification and treatment of the tuberculin converters.

BCG vaccine is intended for use in individuals who have not experienced a prior infection. Therefore, it is not recommended for individuals with a history of natural disease or those who are tuberculin-positive. However, in mass vaccination campaigns, it has been determined that prior tuberculin testing is unnecessary and that vaccine administration to tuberculin-positive individuals under these circumstances does not result in complications of any significance.

BCG vaccination is not recommended for laboratory personnel, including those working with mycobacteria.

2.2 Dose According to manufacturers' instructions; usually administered by multiple pressure method.

2.3 Immunity The duration and degree of protection after vaccination may vary in different circumstances. Protection was found to extend for more than 10 years in at least one trial. Protection following vaccination may persist longer than associated tuberculin sensitivity, and disappearance of tuberculin sensitivity is not conclusive evidence that protection is no longer present.

Revaccination has been recommended in the past when postvaccination tuberculin hypersensitivity waned. Current evidence regarding the poor correlation between protective effect and persistence of hypersensitivity suggests that revaccination is unnecessary.

2.4 Laboratory

Problems

With proper safety precautions and careful technique, the risk of developing mycobacterial infection in the laboratory is low. Monitoring laboratory personnel with periodic tuberculin testing is recommended so that, if infection with virulent *M. tuberculosis* occurs, treatment with isoniazid can be given to prevent the development of clinically manifest disease. A total of 174 laboratory infections have been reported.

3. Contraindications There are no specific contraindications to BCG vaccination, although in individuals with impaired host defenses (immunologic insufficiency states) and with severe dermatitis, complications may be more likely.

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BOTULINUM TOXOID, PENTAVALENT (ABCDE)

1. Description

1.1 Composition

Botulinum Toxoid, Pentavalent (ABCDE) Aluminum Phosphate Adsorbed, is a combination of aluminum phosphate adsorbed toxoids derived from formalin-inactivated types A,B,C,D, and E botulinum toxins. Final product contains no more than 0.025% free formaldehyde. Thimerosal 1:10,000 is added as a preservative.

1.2 License

Unlicensed; limited to investigational use. Approved as IND.

1.3 Storage

Store at 2–10°C; do not freeze.

1.4 Supplier

Immunobiologics Activity, Biological Reagents Section, Laboratory Division, CDC.

1.5 Reactions

Mild systemic reactions can be anticipated after 0.5% of injections. Moderate or severe systemic reactions are not anticipated and should be reported by telephone or air mail to the supplier.

1.6 Efficacy

Experience has shown that: (1) botulinum toxoid is effective in protecting animals against intra-peritoneal challenge with *Clostridium botulinum*, (2) the serum antitoxin levels in animals as determined by mouse protection test correlate with protective activity, and (3) the toxoid introduced into man produces levels of antitoxin thought to be protective. These levels are established arbitrarily by extrapolation of data derived from laboratory animals.

In an experimental study with human volunteers, 30 persons were immunized on a 0–2–12 week schedule with the present lot of toxoid (listed in the references as Toxoid ABCDE–6).^{1,2} Antitoxin content was determined at 14 weeks, 2 weeks after the initial series was completed. Of the 30 persons immunized, 90% had protective levels of Type A antitoxin; 93%, of Type B; 100%, Type C; 79%, Type D; and 100%, Type E. All titers declined after 14 weeks. Only a small percentage of individuals had measurable titers at 52 weeks, before a booster injection was given. However, 8 weeks after the booster injection, protective levels of antitoxin for all five types were found in 100% of individuals.

2. Recommendations

2.1 General

Recommended only for those whose laboratory activities might reasonably be expected to include direct contact with *C. botulinum* under conditions of its toxin production or indirectly with the toxin itself. Not regularly indicated for more casual contacts such as members of maintenance or support staffs.

2.2 Dose

Primary: 0.5 ml. *deep* subcutaneously at 0–2–12 weeks. (The first injection is represented by "0" week. There is a 2-week interval between the first and second injections and a 12-week interval between the first and third.)

Initial Booster: 0.5 ml. *deep* subcutaneously 12 months after the first injection of the primary series.

Subsequent Boosters: 0.5 ml. *deep* subcutaneously at 2-year intervals.

SHAKE WELL before withdrawing each dose. *Do not inject intracutaneously or into superficial subcutaneous structures.*

2.3 Immunity

Antibody responses to toxoid can only be determined by biological tests. Normally, when recommended schedule is followed, the predictability of adequate responses is such that confirmation is not necessary.

2.4 Laboratory Problems

Laboratory accidents involving the toxins of *C. botulinum* are extremely rare. The primary concern is ingestion of toxin, although, theoretically, toxin sufficient to produce illness might be absorbed by inhalation of a heavy aerosol. No laboratory-acquired illness has ever been reported. The toxoid is credited with having protected immunized personnel against known accidental major exposures to cutaneous contact, inhalation, and aspiration.

3. Contraindications Precautions

Toxoid should not be continued in anyone experiencing an unusually severe response to a dose. Reduced dose may be used for one who has experienced only a moderately untoward reaction and requires the toxoid.

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CHOLERA VACCINE

1. Description

1.1 Composition

Cholera vaccine is a phenol-killed suspension containing four billion cells each of classic Inaba and Ogawa serotypes.

1.2 License

Licensed

1.3 Storage

For optimal storage, refrigerate, but refrigeration is not essential.

1.4 Supplier

Several, including Merck, Sharp, and Dohme, Eli Lilly and Co., The National Drug Co., and others.

1.5 Reactions

Adverse reactions of a serious nature are practically unknown. Mild systemic reactions consisting of fever up to 101°, headache, and malaise are common. After 12-36 hours mild to moderate site reactions, consisting of heat, redness, swelling, and tenderness, are very common.

1.6 Efficacy

Efficacy has been documented in several well-controlled studies. See references.

2. Recommendations

2.1 General

There is no known special advantage of any one vaccine over any other.

The vaccine is recommended for individuals who may be exposed to *Vibrio cholerae* in food or fluids, and for laboratory workers and caretakers intimately exposed to the organism.

The vaccine is specifically recommended for:

- (a) Persons who work directly with the disease agent in the laboratory.
- (b) Caretakers of infected animals.

These groups *need not be* vaccinated:

- (a) Persons who work in the same laboratory though not with the specific organism.
- (b) Personnel who handle media and glassware.
- (c) Laboratory and animal quarter maintenance personnel.
- (d) Other persons who enter laboratory or animal-care areas where work is under way with the organism.

2.2 Dose

Primary: two doses, 0.5 ml. and 1.0 ml., subcutaneously, from 1 week to, preferably, 1 month or more apart.

Booster: 1.0 ml. (or dose recommended by manufacturer) at 6-month intervals if there is continuing exposure or at unspecified intervals as needed to protect against exposure.

2.3 Immunity

Immunity can be assessed by quantitative serologic studies. The most feasible test is the vibriocidal antibody titration. The vaccine offers good protection for 3-6 months. No skin tests correlate with immunity.

2.4 Laboratory Problems

Laboratory accidents are extremely rare. Nine cases have been reported. The writer is personally familiar with three laboratory-acquired infections, two of which occurred at

Walter Reed Army Institute of Research (JAMA, 197:99, 1966) and one at the Colindale Laboratory in London. The latter is unpublished. In the cases at Walter Reed, there is reason to believe that accidental ingestion of broth cultures was responsible. No information is available on the Colindale case. Most laboratory workers agree that the only serious danger to laboratory workers is the possibility of aspirating a broth culture or eating food contaminated by soiled hands.

3. Contraindications

Precautions

There are no known contraindications to the use of the vaccine, although some believe that it should not be given to pregnant women because of the unknown risk to the fetus.

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2. Laboratory Accidents

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DIPHTHERIA AND TETANUS TOXOIDS

1. Description

- 1.1 Composition** Diphtheria and tetanus toxoids are prepared by formaldehyde treatment of the respective toxins. The toxoids are available in both fluid and adsorbed forms. All preparations contain comparable amounts of tetanus toxoids, but the diphtheria component of the adult type tetanus and diphtheria toxoids (Td) approximates 10% of that contained in the standard DTP preparations.
- 1.2 License** Diphtheria and tetanus toxoids are licensed singly and in various combinations. The most important products for practical use are: (1) tetanus and diphtheria toxoids, adult type (Td); and (2) tetanus toxoid (T).
- 1.3 Storage** Refrigerate diphtheria and tetanus toxoids.
- 1.4 Supplier** Tetanus and diphtheria toxoids, adult type (Td), are manufactured by Cutter Laboratories, Eli Lilly and Co., Lederle Laboratories, The National Drug Co., and Wyeth Laboratories. In addition, many state health department laboratories produce these toxoids for use in their respective states.
- 1.5 Reactions** Reactions to diphtheria and tetanus toxoids, given either singly or in combination, are rare. Two general types of reactions occur: (1) a local swelling, pruritus, and tenderness at the site of injection or (2) a more generalized phenomenon such as fever, urticaria, or angioneurotic edema. Reactions are more common in older children or adults, and there is a strong association between reactions and high circulating antitoxin titers.
- 1.6 Efficacy** Extensive experience has shown that diphtheria and tetanus toxoids decrease the incidence and mortality of these diseases and reduce complications stemming from them.

2. Recommendations

2.1 General

Comparative tests of diphtheria and tetanus toxoids have shown that adsorbed toxoids are clearly superior in antibody titer produced and in the duration of protection achieved. The promptness of antibody responses following the administration of either fluid or adsorbed toxoids as boosters is not sufficiently different to be of clinical importance. Therefore, adsorbed toxoids are the agents of choice for primary and booster immunizations. Based on data about effectiveness, primary immunization of older children and adults, and increasing reactions to full doses of diphtheria toxoids with age, the adult type Td is considered the agent of choice for immunization of persons over 6 years of age. The use of this preparation obviates the need for Schick or Moloney testing before immunization.

All adults should have protection against diphtheria and tetanus. This includes appropriate booster doses at specified time intervals.

2.2 Dose

Primary for unimmunized adults: a single dose of adult type Td given intramuscularly or subcutaneously on two occasions at 4-6 week intervals with a reinforcing dose approximately 1 year after the second dose.

Booster: a single dose of this same preparation every 10 years (if a dose is given sooner as part of wound management—see below—the next booster is not needed for another 10 years). More frequent booster doses are not indicated and may be associated with increased reactions.

2.3 Immunity

An important part of *wound management* is the prevention of tetanus. Evidence demonstrates that complete primary immunization with tetanus toxoid provides very long protection. Therefore in such an individual *no* booster is needed for a possibly tetanus-associated injury if the most recent dose of Td was given in the past year or so. In cases where previous tetanus immunization status is questionable or unknown, the outline of procedures recommended by the PHS Advisory Committee on Immunization Practices (August 1969) should be consulted.

2.4 Laboratory Problems

Forty cases of laboratory-acquired diphtheria and six of laboratory-acquired tetanus have been reported.

3. Contraindications Precautions

Although specific contraindications to the use of these vaccines have not been outlined, administration of these agents should be postponed in the face of severe febrile illness. History of severe reaction to a previous dose may argue against continued use of the vaccine. Each such case must be evaluated on an individual basis.

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EASTERN EQUINE ENCEPHALITIS (EEE) VACCINE

1. Description

- 1.1 Composition Eastern equine encephalitis (EEE) vaccine is a formalin-inactivated, lyophilized product prepared from the supernatant maintenance fluid of primary chicken embryo cell cultures infected with the Walter Reed Army Institute of Research PE6 strain of EEE virus. Cell cultures are grown in Eagle's basal medium containing 200 units of penicillin and 50 ug. of streptomycin per ml. Twenty-four hours before inoculation of the seed virus, the antibiotic-containing growth medium is replaced with antibiotic-free medium 199. The vaccine contains 0.25% Human Serum Albumin (USP) as a virus stabilizer.
- 1.2 License Unlicensed; approved as IND.
- 1.3 Storage Store lyophilized product at -20°C .
- 1.4 Supplier Immunobiologics Activity, Biological Reagents Section, Laboratory Division, CDC.
- 1.5 Reactions Serious local or systemic reactions have not been observed in a limited number (less than 1,000) of vaccinees. A few mild reactions have been recorded. These consisted primarily of local myalgia and malaise and, in a few instances, headaches and arthralgia.
- 1.6 Efficacy No published data are available. The U.S. Army has tested the vaccine in several animal species for purity and safety and has tested the vaccine in several hundred humans. It is approved by the U.S. Army for use in military personnel at high risk (18th Meeting of the Committee on Immunizations, Oct. 24, 1967, Department of the Army, Fort Detrick, Frederick, Maryland).

2. Recommendations

- 2.1 General Recommended for individuals who may be exposed to EEE virus and personnel who are at high risk because of their laboratory or field studies.

The vaccine is specifically recommended for:

- (a) Persons who work directly with the disease agent in the laboratory.
- (b) Persons who work in the same laboratory though not with the specific organism.
- (c) Caretakers of infected animals.
- (d) Personnel who handle contaminated media and glassware before autoclaving.

Other persons who enter laboratory or animal-care areas where work is underway with the organism *need not be vaccinated*.

- 2.2 Dose Primary: two doses of 0.5 ml. each administered subcutaneously 29 days apart.

2.3 Immunity

2.4 Laboratory Problems

3. Contraindications Precautions

Booster: 0.1 ml., administered intrademally, annually.

Immunity can be assessed by quantitative serologic studies. The most stringent test is the constant serum-virus dilution test conducted by the intracerebral inoculation of 3-week-old mice. A circulating antibody titer of ≥ 2.0 logs virus neutralization is considered good evidence of significant immunity.

Laboratory accidents with EEE virus are rare. The writer is aware of only two reported cases, neither of which was fatal. However, the potential of EEE virus producing severe or fatal infection makes it desirable to vaccinate for this virus.

The vaccine may be contraindicated in persons with high sensitivity to egg material.

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**IMMUNE SERUM GLOBULIN FOR PROTECTION
AGAINST VIRAL HEPATITIS**
**RECOMMENDATION OF THE PUBLIC HEALTH SERVICE
AGAINST VIRAL HEPATITIS**

INTRODUCTION

The term "viral hepatitis" as commonly used applies to 2 diseases that are clinically quite similar but virologically, immunologically, and epidemiologically distinct. These diseases are hepatitis-A (formerly infectious hepatitis) and hepatitis-B (formerly serum hepatitis). Any other viral infection that affects the liver, producing an inflammatory response or "hepatitis" is not customarily included under the term viral hepatitis.

Immune serum globulin (ISG) is highly effective protection against the clinical manifestations of hepatitis-A but ineffective for hepatitis-B. Therefore, accurate diagnosis of the kind of viral hepatitis, insofar as is possible with methods presently available, is crucial to the effective use of ISG. Clinically, it is extremely difficult to distinguish between individual cases of hepatitis-A and hepatitis-B, but discrimination between these diseases often is possible, based on careful evaluation of epidemiologic evidence and blood tests for hepatitis-B.

Viral hepatitis is often acquired as a result of a particular kind of exposure, and terms such as "transfusion-associated," "hemodialysis-associated," "chimpanzee-associated," and "syringe-" or "needle-associated," help characterize the mode of transmission.

Hepatitis-A

Hepatitis-A is thought to be caused by a virus transmitted principally by the fecal-oral route under conditions of poor sanitation and close contact with infected persons. Characteristically, the illness produced is of abrupt onset with fever, malaise, anorexia, nausea, abdominal discomfort, and jaundice. Morbidity is variable and mortality quite low (less than 1 percent). The usual incubation period of hepatitis-A is 15-50 days (average 25-30). Stools from patients with hepatitis-A have been shown to be infective as long as 2-3 weeks before and 2 weeks after the onset of jaundice. Blood is infective at least 2 weeks before but less than 1 week after the appearance of jaundice, so parenteral transmission of hepatitis-A is also possible.

Hepatitis-B

Hepatitis-B is thought to be caused by a virus, distinctive from that associated with hepatitis-A, trans-

mitted principally by parenteral routes. Insidious onset of illness, anorexia, malaise, nausea, vomiting, abdominal discomfort, and jaundice are characteristic. Morbidity is variable; mortality exceeds that of hepatitis-A. Exposure is usually through blood transfusion or contaminated needles. The incubation period is characteristically long, usually 2-6 months; however, some hepatitis-B cases with incubation periods as short as 1-2 months have been observed. Non-parenteral transmission of hepatitis-B also occurs and probably contributes to the occupational hazard for those who work in blood banks, or renal dialysis units, or are otherwise in direct contact with infective blood. The exact mechanism and frequency of these non-parenteral transmissions are under intensive study.

Virus-like particles, termed the hepatitis-B antigen (HBAG), have been detected in the serum of many patients with hepatitis-B. These particles (which were originally tagged "Australia antigen" and then "hepatitis-associated antigen") appear to persist from about 4 weeks before onset of jaundice to 4-5 weeks or more after onset. In a small proportion of patients, and HBAG-carrier state develops. HBAG is found in a large proportion of patients with transfusion-associated hepatitis and with hepatitis associated with parenteral drug abuse. It is detectable in hepatitis patients who cannot recall any possible parenteral exposure and in some completely asymptomatic persons.

Blood with HBAG is very likely to be infective. Blood banks use HBAG detection in screening programs aimed at eliminating hepatitis-B transmission through blood transfusion. Antibody to HBAG (anti-HBAG or HBAb) in the serum of hepatitis-B patients during convalescence has been demonstrated. Its role in protection is under investigation.

Hepatitis Surveillance

Viral hepatitis has been a nationally reportable disease since 1952. Since 1966 the 2 kinds of hepatitis have been listed separately. The annual total number of viral hepatitis cases has varied somewhat cyclically between 14,922 (1957) and 72,651 (1961); there were peaks in 1954 and 1961 and a gradual increase in incidence since the most recent nadir in 1966 (34,356 cases). A total of 69,636 viral hepatitis cases were reported in 1971; 8,879 were presumed on epidemiologic grounds to be hepatitis-B. The other 60,757 were hepatitis-A and possibly other viral diseases or hepatitis-B cases that were epidemiologically unconfirmed.

*From the June 10, 1972, issue of the *Morbidity and Mortality Weekly Report*, a publication of the Bureau of Epidemiology, CDC, Vol. 21, No. 23, pp. 194-197.

In the last 5 years, several important changes in epidemiologic trends were observed in the characteristics of reported cases: hepatitis used to occur predominantly in winter and spring, but the seasonal variation has diminished remarkably; the age distribution has shifted from a peak in persons age 5-14 to those 15-24; an equal proportion of cases between the sexes has changed to a 2:1 male preponderance among patients 15-24 years; and the general rural to urban trend has been notable. During the same 5-year period, the rate of increase in reported cases was greater for hepatitis-B than hepatitis-A. These changes have paralleled the recognized rise in illicit use of parenteral drugs.

IMMUNE SERUM GLOBULIN

Immune serum globulin* (ISG) is a sterile solution containing antibody derived from human blood for **intramuscular** use. It is 16.5 percent protein obtained by cold alcohol fractionation of large pools of blood plasma. It contains specified amounts of antibody against diphtheria, measles, and one type of poliovirus. Neither hepatitis-A nor hepatitis-B has been transmitted by ISG.

ISG and Hepatitis-A

Numerous field studies during the past 2 decades have documented the protection against hepatitis-A conferred by ISG administered before exposure or during the incubation period. Its relative effectiveness depends on timing and dose. When administered before or within 1-2 weeks after exposure to hepatitis-A in the appropriate dose, it prevents illness in 80-90 percent of those exposed. However, because ISG may not suppress inapparent infection, long-lasting, natural immunity may result.

The decision to give ISG is based on assessing the possible hepatitis exposure. If the exposure could have resulted in infection, ISG should be given.

ISG should be given as soon as possible after a known exposure. Its prophylactic value is greatest when given early in the incubation period and decreases with time after exposure. The use of ISG more than 6 weeks after exposure or after onset of clinical illness in a contact is not indicated.

Dosage

The dosage patterns of ISG in common use were derived primarily from field and clinical observations. Under most conditions of exposure, protection is afforded by intramuscular injection of 0.01 ml of ISG per pound of body weight (approximately 0.02 ml/kg) (Table 1).

*Official name: Immune Serum Globulin (Human)

Specific Recommendations

Household Contacts: Close personal contact, as among permanent and even temporary household residents, is important in the spread of hepatitis-A. Secondary attack rates are particularly high for children and teenagers. Rates are somewhat lower for adults, but illness tends to be more severe. ISG is recommended for all household contacts who have not already had hepatitis-A.

Table 1

Guidelines for ISG Prophylaxis Against Hepatitis-A

Person's Weight (lb.)	ISG Dose (ml)*
50	0.5
50-100	1.0
100	2.0

*Within limits, larger doses of ISG provide longer-lasting but not necessarily more protection. More ISG is, therefore, prescribed under certain circumstances. (See **Institutional Contacts and Travelers to Foreign Countries**)

School Contacts: Although the highest incidence of hepatitis is among school-age children, contact at school is usually not an important means of transmitting this disease. Routine administration of ISG is not indicated for pupil or teacher contacts of a patient. However, when epidemiologic study has clearly shown that a school- or classroom-centered outbreak exists, it is reasonable to administer ISG to persons at risk.

Institutional Contacts: In contrast to schools, the conditions in institutions, such as prisons and facilities for the mentally retarded, favor transmission of hepatitis-A. Sporadic cases as well as epidemics in such institutions have been reported frequently. ISG administered to patient and staff contacts of hepatitis-A patients in the doses shown in Table 1 can effectively limit the spread of disease.

Where hepatitis-A is endemic, particularly in large institutions with high rates of admission and discharge, all who live and work there (residents and staff personnel) may be subject to continuing exposure. Under these circumstances, ISG has not resulted in eradication of hepatitis, but it has provided temporary protection against hepatitis-A when administered in doses of 0.02-0.05 ml/lb at the time of admission or employment. Re-administration of ISG in the same dose every 6 months may be necessary as long as the risk persists.

Hepatitis-B, which is not affected by ISG, may also be endemic in such institutions; therefore, the type of hepatitis should be identified by epidemiologic and serologic methods before considering routine, general use of ISG (see **ISG and Hepatitis-B**).

Hospital Contacts: Routine prophylactic administration of ISG to hospital personnel is not indicated. Emphasis should be placed on sound hygienic practices. Intensive, continuing education programs pointing out the risks of exposure to hepatitis-A and the recommended precautions should be directed toward hospital personnel who have close contact with patients or infective materials.

Hemodialysis: Most of the hepatitis affecting patients and the staff of renal hemodialysis units appears to be hepatitis-B and therefore not preventable by ISG (see ISG and Hepatitis-B).

Needle Exposure: For a person accidentally inoculated with blood or serum from a hepatitis patient, ISG prophylaxis should be used only if the inoculum is suspected of containing hepatitis-A. Then, ISG should be given in the dose specified in Table 1.

Office and Factory Contacts: Routine administration of ISG is not indicated for persons exposed in the usual office or factory situation to a fellow worker with hepatitis.

Common-Source Exposure: When food, water, or other such vehicle is clearly identified as a common source of infection for multiple hepatitis cases, administration of ISG should be considered for others exposed.

Exposure to Non-Human Primates: Sporadic cases and outbreaks of hepatitis have occurred among persons in close contact with recently imported non-human primates, primarily chimpanzees. Because of the similarity between chimpanzee-associated hepatitis and hepatitis-A, prophylactic ISG has been used with apparent success in doses of 0.02 ml/lb (0.05 ml/kg) administered every 4 months to those in close contact with newly imported animals. Emphasis should also be placed on other measures, such as scrupulous hygienic practices, use of protective clothing, and limitation of human contact with the animals.

Travelers to Foreign Countries: The risk of hepatitis-A for United States residents traveling abroad appears to be small; it varies with living conditions, the prevalence of hepatitis in the areas visited, and particularly the length of stay.

Travelers may be at no greater risk than in the United States when their travel involves ordinary tourist routes and lasts less than 3 months; ISG is not routinely recommended for them. However, travelers to tropical areas and developing risk of acquiring hepatitis-A. If ISG is administered, the dosage schedule in Table 1 should apply.

Travelers planning to stay (3 or more months) in tropical areas or developing countries where hepatitis-A is common and where they may be exposed to infected

persons and contaminated food and water are at greater risk of acquiring hepatitis. A single dose of ISG as shown in Table 2 is recommended for them. (Data are inadequate to specify precise boundaries.)

Table 2

Guidelines for U.S. Travelers Planning to Stay 3 or More Months in Tropical Areas or Developing Countries

Person's Weight (lb.)	ISG Dose (ml)
50	1.0
50-100	2.5
100	5.0

For persons residing abroad in tropical areas or developing countries, the risk of hepatitis appears to persist. Experience has shown that regular administration of ISG offers at least partial protection against hepatitis. It is recommended that prophylactic ISG be repeated every 4-6 months at doses indicated in Table 2.*

Pregnancy: Pregnancy is not a contraindication to using ISG as recommended.

Reactions

ISG should **not** be administered intravenously because of the possibility of severe hypersensitivity reactions.

Intramuscular administration of ISG rarely causes adverse reactions. Discomfort may occur at the site of injection, especially with larger volumes. A few instances of hypersensitivity have been reported, but in view of the very large number of persons who have received ISG, the risk is exceedingly small. Antibody against gamma globulin may appear following administration of ISG, although its significance is unknown. When ISG is indicated for the prophylaxis of hepatitis-A, this theoretical consideration should not preclude its administration.

ISG and Hepatitis-B

Numerous well-constructed studies have attempted to document the protective effect of standard immune serum globulin against hepatitis-B. Evidence indicates that there is no protective effect. Therefore, ISG should not be used for protection against so-called transfusion-associated hepatitis. It should not be administered routinely to patients and staff members of hemodialysis units, to other persons exposed to hepatitis-B, or to

*Some agencies have used up to 0.05 ml/lb each 4 to 6 months rather than the 5 ml for adults recommended here.

hepatitis-B carriers. The lack of effect of ISG against hepatitis-B is presumably related to insufficient titer or complete absence of specific antibody against hepatitis-B in most lots of commercial ISG. Whether or not administration of hyperimmune globulin containing large amounts of HBAb will prove effective in modifying hepatitis-B has yet to be determined.

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INFLUENZA VACCINE

1. Description

1.1 Composition

Presently available influenza vaccine is a formalin-inactivated product of varying composition, depending on the influenza virus strains forecast to be prevalent. Standard vaccine is prepared from a concentrated suspension of virus grown in embryonated chicken eggs. Highly purified products are prepared by zonal-centrifugation or other processes.

1.2 License

Licensed.

1.3 Storage

Refrigerate at 2° to 8°C.

1.4 Supplier

Multiple producers in the United States.

1.5 Reactions

Local reactions of tenderness and induration are reported in 25 to 50% of adult vaccinees, depending on the product administered. Highly purified vaccines produce considerably fewer reactions. Systemic complaints of malaise, myalgias, and fever are less common, but do occur in a small proportion of adult vaccinees following administration of standard vaccines. All reactions are more common in children than in adults.

1.6 Efficacy

Efficacy of properly constituted, potent, inactivated influenza vaccine has been shown to be, at best, moderate under field conditions. Vaccines commonly contain both types A and B influenza virus antigens, selected annually to represent contemporary strains. A precise relationship between vaccine strains and those which may occur is at times problematic. The relationship directly influences vaccine effectiveness. Under favorable conditions, inactivated vaccines achieve up to 70% clinical effectiveness. Lower levels are commonly observed.

2. Recommendations

2.1 General

Because of technological limitations in achieving satisfactory results with currently available inactivated influenza vaccines, annual immunization is generally recommended only for high risk populations. These include patients with chronic debilitating illnesses, particularly of the cardio-respiratory system, and persons in older age groups.

Risk in the influenza virus laboratory is not sufficient for regular vaccination of the staff.

2.2 Dose

Primary for adults: one full dose (volume specified by manufacturer) subcutaneously on two occasions, preferably 6 to 8 weeks apart.

Primary for children: smaller dose than for adults; specified in the manufacturer's labeling.

Booster: when no substantial change has occurred in vaccine composition, individuals who should receive vaccine and who were vaccinated in the preceding year need only a single dose subcutaneously.

- | | |
|-------------------------|--|
| 2.3 Immunity | Immunity following influenza vaccine is difficult to assess because of the continual drift in prevalent viruses. The vaccine apparently induces immunity for at least 6 months. |
| 2.4 Laboratory Problems | Laboratory accidents can occur, but apparently pose no significant problem. Only seven laboratory infections are known. |
| 3. Contraindications | On theoretical grounds, influenza vaccine should not be administered to anyone who has had clearly documented hypersensitivity to egg protein. With highly purified vaccines, the justification for this precaution is more tenuous. |

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MEASLES VACCINE

1. Description

1.1 Composition Measles vaccines currently in use in the United States are live, attenuated, and further attenuated virus vaccines propagated in either chick embryo (attenuated and further attenuated) or canine renal cell (attenuated) culture.

1.2 License Licensed for general use.

1.3 Storage Refrigerate live measles virus vaccines in the lyophilized state.

1.4 Supplier Live attenuated measles virus vaccines are manufactured by Charles Pfizer and Co., Inc., Eli Lilly and Co., Lederle Laboratories, Merck, Sharp, and Dohme, Parke, Davis and Co., and Philips Roxane, Inc.

Further attenuated measles virus vaccines are manufactured by Pitman-Moore and Merck, Sharp, and Dohme.

1.5 Reactions Live attenuated measles virus vaccines administered with Measles Immune Globulin produce fevers of 103°F (rectal) in 15% of recipients beginning on or about the sixth day after vaccination and lasting no longer than 5 days. Similar febrile reaction rates are reported for the further attenuated vaccines. About twice as many (30%) of those receiving attenuated vaccines without Measles Immune Globulin have similar responses. Characteristic measles rash has been reported in 5-10% of recipients. The vaccinee with rash is not considered infectious. Other serious reactions associated with vaccine usage have been rare.

1.6 Efficacy Vaccine safety and efficacy have been well documented in controlled field observations.

2. Recommendations

2.1 General Both attenuated and further attenuated vaccines offer satisfactory protection. When using attenuated vaccines, follow the manufacturers' recommendations pertaining to simultaneous administration of Measles Immune Globulin.

Immunization is recommended for all measles-susceptible individuals 12 months of age or older. Vaccination of adults is rarely necessary; nearly all individuals are immune by age 15.

Susceptible individuals working directly with the agent in the laboratory should be vaccinated. Because of the high level of immunity in adults, the risk of acquiring disease for other persons in the laboratory or persons who enter the laboratory or animal care area is extremely low.

2.2 Dose Primary: needs to be given only once; administer according to the manufacturer's directions.

Booster: not needed.

2.3 Immunity Disease history is a relatively reliable single indicator of an individual's susceptibility.

Documented history of immunization is satisfactory. Serologic tests, specifically complement fixation or hemagglutination

inhibition, are useful in documenting an individual's immunity status.

2.4 Laboratory Problems

Laboratory accidents with this agent are extremely rare. Only one laboratory-acquired case has been reported.

3. Contraindications Precautions

Live measles virus vaccines are contraindicated in individuals with leukemia, lymphoma, and other generalized malignancies; individuals with altered immunologic competency (that is, individuals on steroids, alkylating agents, antimetabolites, and radiation therapy); and pregnant women. Vaccination should be postponed if the prospective vaccinee has a severe febrile illness or has received immune globulin within the past 3 months. Any individual with known active tuberculosis should be under treatment when given measles vaccine.

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PLAGUE VACCINE

1. Description

- 1.1 Composition The plague vaccine produced for use in the United States is prepared from *Pasteurella pestis* grown in artificial media, inactivated with formaldehyde, and preserved in 0.5% phenol. Live attenuated vaccines are produced in other countries, but are not commercially available in the United States.
- 1.2 License The inactivated vaccine is licensed for use in the United States.
- 1.3 Storage Refrigerate at 4°C.
- 1.4 Supplier Inactivated vaccine is produced by Cutter Laboratories.
- 1.5 Reactions Adverse reactions consisting of pain, reddening, and swelling at the injection site are frequent. With repeated doses, systemic reactions of fever, headache, and malaise occur more often and tend to become more pronounced. Sterile abscesses are reported to occur rarely. No fatal or disabling complications have been observed.
- 1.6 Efficacy No field trials have been conducted. Experience among immunized U.S. personnel in Vietnam has been favorable.^{2,3}

2. Recommendations

2.1 General

Recommended for all persons traveling to Vietnam, Cambodia, and Laos and for all persons who have field work or vocations which bring them into frequent and regular contact with wild rodents in plague enzootic areas of the western United States, South America, Africa, or Asia.

Routine vaccination is not indicated for persons simply living in plague enzootic areas of the western United States or for travelers going to most of the countries reporting cases.

The vaccine is specifically recommended for:

- (a) All laboratory personnel working with the *Pasteurella pestis* organism or plague-infected rodents.
- (b) Caretakers of infected animals.

These groups *should not be* vaccinated.

- (a) Personnel in a laboratory where work with *Pasteurella pestis* is done but who do not work with the organism.
- (b) Personnel who handle decontaminated media and glassware.
- (c) Laboratory and animal quarters maintenance personnel.

2.2 Dose

All injections should be given intramuscularly.

Primary for adults and children over 10 years old: two doses, 0.5 ml. each, 4 or more weeks apart, followed by a third dose, 0.2 ml., 4 to 12 weeks after the second injection. When less time is available, satisfactory, but less than optimal, results can be obtained with two 0.5 ml. injections administered at least 3 weeks apart.

Primary for children less than 10 years old: three doses smaller than those for adults. The manufacturer's guide to proportions

of the adult dose for children is: infants under 1 year, 1/5 adult dose; 1-4 years, 2/5 adult dose; 5-10 years, 3/5 adult dose. The intervals between injections for children are the same as for adults.

Booster: every 6 to 12 months while individuals remain in an area where the risk of exposure persists. Satisfactory doses for children and adults are the same volumes suggested for the third dose in the primary series. The primary series need never be repeated for booster doses to be effective. If a booster dose produces severe local or systemic reactions, subsequent boosters may not be necessary provided immunity is adequate as measured by the tests mentioned under "Immunity" (below).

Summary: The following table summarizes the recommended doses for primary and booster vaccinations:

Dose Number	AGE (YEARS)			
	Under 1	1-4	5-10	Over 10
1 & 2	0.1 ml.	0.2 ml.	0.3 ml.	0.5 ml.
3 & Boosters	0.04 ml.	0.08 ml.	0.12 ml.	0.2 ml.

2.3 Immunity

Immunity can be assessed by a passive hemagglutination test or the mouse protective index.^{1,2,1.3} The mouse protective index is considered the better measure of protection.

2.4 Laboratory Problems

Accidental infection of laboratory workers occurs infrequently; only three such cases have been reported in the United States since 1900.^{1.1}

3. Contraindications Precautions

There are no known contraindications to the use of the vaccine, although repeated doses may produce reactions which preclude further injections.

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POLIOMYELITIS VACCINE

1. Description

1.1 Composition Two basic types of poliomyelitis vaccines are currently in use in the United States. These are: (1) inactivated polio virus vaccine (IPV) and (2) live, attenuated oral vaccine (OPV).

IPV is prepared by formalin-inactivation of the three types of polio virus grown in tissue culture of monkey kidney cells.

OPV is prepared from virus propagated on green monkey kidney cells and is marketed in monovalent preparations of Type 1, Type 2, and Type 3 and in a trivalent preparation.

1.2 License Both IPV and OPV are licensed.

1.3 Storage Refrigerate IPV. Store OPV in the frozen state (-20°C.)

1.4 Supplier IPV is made by Charles Pfizer and Co., Inc., Eli Lilly and Co., Parke, Davis and Co., and Pitman-Moore.

1.5 Reactions Immediate reactions to poliomyelitis vaccines have not been reported. Very rarely, cases of paralytic poliomyelitis have occurred in recipients of OPV or their close contacts within 30 days of vaccine feeding. Careful analysis indicates no more than one case of "vaccine-associated" paralytic disease for every 3 million doses of OPV administered.

1.6 Efficacy The efficacy and safety of both IPV and OPV have been well established in controlled field studies.

2. Recommendations

2.1 General OPV is now more widely used in this country than IPV not only because it is easier to administer but also because it produces an immune response which, without regular booster doses, appears to be similar to immunity induced by natural polio virus infection. Trivalent OPV has largely replaced monovalent forms because it offers simplified scheduling and record keeping. A primary series of trivalent OPV will produce an immune response for all polio virus types in well over 90% of the recipients.

Primary immunization of infants, children, and adolescents should be routine practice. Routine poliomyelitis immunization for adults in the continental United States is not recommended because of the extreme unlikelihood of exposure. However, any unimmunized adult who is at increased risk by virtue of contact with a known case or travel to epidemic or endemic areas should receive trivalent OPV according to the schedule outlined below. Persons employed in medical laboratories may well be considered at increased risk.

All persons working directly with the agent, all persons working in the same laboratory, animal caretakers, and other persons entering the laboratory or animal care areas should be protected with OPV.

2.2 Dose

IPV

Primary for adults: four parenteral doses. The first three are

administered at monthly intervals and the fourth, a reinforcing dose, 6-12 months after the third.

Booster: single doses every 2-3 years to assure adequate levels of antibody. The need for IPV boosters can be obviated by a full course of OPV.

OPV

Primary for adults: three doses, the first two doses given at 6-8 week intervals, and the third, 8-12 months after the second.

Booster: no indication at present for regular or routine booster doses of OPV.

2.3 Immunity

In determining an individual's immunity, a documented history of full OPV immunization is satisfactory. Serologic tests, specifically neutralization titers, are helpful.

2.4. Laboratory Problems

Nine laboratory-acquired cases have been reported.

3. Contraindications Precautions

Pregnancy is not an indication for vaccine administration nor is it a contraindication when immunization is deemed necessary. There are no specific contraindications to the use of poliomyelitis vaccines. The routine immunization for adults in the United States currently is not necessary, and the rare complications of "vaccine-associated" cases have been discussed.

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Q FEVER VACCINE

1. Description

- 1.1 Composition Q fever vaccine is prepared from yolk sacs infected with *Coxiella burnetii*. It is dehydrated. Two batches are available: one with the organisms in Phase I, the other with them in Phase II.
- 1.2 License Unlicensed.
- 1.3 Storage For optimal storage, refrigerate, but refrigeration is not essential.
- 1.4 Supplier Walter Reed Army Institute for Research.
- 1.5 Reactions Severe local reactions with systemic manifestations occur in 1-2% of persons without known history of Q fever or Q fever vaccination; these reactions are much more frequent in persons exposed to Q fever or previously vaccinated with Q fever vaccine. The reaction consists of swelling and tenderness, often involving the entire upper arm, mild fever, and malaise. Reactions to egg proteins are also possible, and individuals should be questioned about tolerance to eggs.
- 1.6 Efficacy No field trials have been conducted. Unpublished human volunteer experiments with Phase II challenge are favorable. Experience in rickettsial laboratories is favorable. Phase I vaccine probably gives somewhat better protection against Phase I organisms (wild type).

2. Recommendations

- 2.1 General Recommended primarily for personnel in rickettsial laboratories; not recommended for general use.

The vaccine is specifically recommended for:

- Laboratory personnel who work directly with the disease agent.
- Persons who work in the same laboratory or whose work brings them into the area.
- Caretakers of infected animals.
- Laboratory and animal quarters maintenance personnel.
- Persons who enter the area where Q fever work is done.

Personnel who handle media, glassware, or laundry *need not* be vaccinated if these materials are autoclaved on removal from the laboratory.

2.2 Dose

Phase II Vaccine

Primary: 0.1 ml., followed in 4 days by 1.0 ml. and in another 7 days by 1.0 ml. Before the second and third injections, the previous site(s) should be palpated, and the vaccinee should be questioned. If swelling, heat, and tenderness are present, no further injections should be given.

Booster: none.

Phase I Vaccine

Primary: follow the schedule for Phase II vaccine but give 0.6 ml. for the second and third injections.

Booster: none.

2.3 Immunity

There are no practical tests for immunity. All persons are considered susceptible unless they have been immunized or infected.

2.4 Laboratory Problems

With 184 reported laboratory-acquired infections, this organism is the third most frequent cause of laboratory infection. The rickettsia of Q fever survives drying and can cause infections in personnel located on other floors or in persons exposed in other buildings to material (such as laundry) from the rickettsial laboratory. Most infections are relatively mild, but about a third of those infected have fever for a week or more, and some are severely ill.

3. Contraindications Precautions

The vaccine should not be given to persons who have been previously infected with Q fever or who have received Q fever vaccine. Neither should it be given to persons who are sensitive to eggs. Each prospective vaccinee should be asked if he can eat eggs.

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RABIES VACCINE*

1. Description

- 1.1 Composition The rabies vaccine available for human use is Duck Embryo Vaccine (DEV).

DEV is composed of a 10% suspension of embryonated duck eggs infected with fixed virus and inactivated with beta-propiolactone. The suspending fluid consists of 0.1% gelatin and 0.25% dibasic potassium phosphate. The vaccine is preserved with thimerosal, 1:10,000.

- 1.2 License Licensed.

- 1.3 Storage Refrigerate (2-5°C.).

- 1.4 Supplier Eli Lilly and Co.

- 1.5 Reactions Erythema, pruritus, pain, and tenderness at the site of inoculation are common. Systemic reactions, including low grade fever, or, rarely, shock, may occasionally occur late in the course of therapy, usually after five to eight doses. In rare instances, serious reactions have occurred after the first dose, particularly in persons previously sensitized with vaccine containing avian tissue.

Neurologic complications have been reported for one of every 25,000 persons treated. One death, possibly related to the vaccine, has occurred among some 250,000 who have received DEV.

When rabies vaccine must be given to a person with a history of hypersensitivity, especially to avian tissues, antihistaminic drugs should be used. Epinephrine is helpful in reactions of the anaphylactoid type.

When meningeal or neuromyolytic reactions develop, vaccine treatment should be discontinued altogether. Corticotrophin or corticosteroids are used for such complications.

- 1.6 Efficacy In the United States, effectiveness can only be judged by frequencies of failure to prevent disease. During the years 1957 through 1967 when Nervous Tissue Vaccine (NTV) as well as DEV were available, there were six rabies deaths among the 117,000 NTV-treated persons (1:19,600) and seven deaths among 172,000 treated with DEV (1:24,500).

2. Recommendations

- 2.1 General Recommended for use in high risk groups of individuals as a preexposure immunizing vaccine and in postexposure prophylaxis.

The relatively low frequency of reactions to DEV has made it more practical to offer preexposure immunization to persons

* See recommendations, page II- , regarding the hazards of using Challenge Virus Standard (CVS) and Production Virus (PV) in the laboratory and immunization standards.

in high risk groups: veterinarians, animal handlers, certain laboratory workers, and personnel stationed in areas of the world where rabies is a constant threat. Others whose vocational or avocational pursuits result in frequent exposure to dogs, cats, foxes, skunks, or bats should also be considered for preexposure prophylaxis.

Persons who work directly with rabies virus in laboratories, those who work in the same laboratories but not with the rabies virus, and caretakers who are in direct contact with animals infected or potentially infected with the disease agent should obtain preexposure immunization and have a detectable serum neutralizing antibody titer to rabies before undertaking such work. They should receive a booster injection each year.

Persons who handle media, glassware, and other material from laboratories in which the agent is studied and laboratory and other animal maintenance personnel should receive pre-exposure immunization; a booster every 2-3 years rather than annually is required.

Visitors to areas where rabies studies are conducted should receive preexposure immunization; boosters are necessary for those previously immunized. Only those who have received booster shots every 2-3 years should be allowed continuing entry.

Postexposure prophylaxis

Primary: at least 14 single, daily injections in the dose recommended by the manufacturer. These should be given subcutaneously in the abdomen, lower back, or lateral aspect of the thighs; rotation of sites is recommended.

For severe exposures, 21 doses of vaccine are recommended. These may be given in 21 daily injections or as 14 doses during the first 7 days (either in two separate injections or in double doses), the remaining doses being given singly during the next 7 days.

Booster: two booster doses, one 10 days and the other at least 20 days after completion of the primary course. The two booster doses are particularly important if antirabies serum was used in the initial therapy.

Preexposure prophylaxis

Primary: two 1.0 ml. injections of DEV given subcutaneously in the deltoid area 1 month apart followed by a third dose 6 to 7 months after the second dose. This series of three injections can be expected to produce neutralizing antibody in 80 to 90% of vaccinees 1 month after the third dose.

If more rapid immunization is desirable, three 1.0 ml. injections of DEV may be given at weekly intervals with a fourth dose 3 months later. This schedule elicits an antibody response in about 80% of the vaccinees.

2.2 Dose

Booster: all persons receiving the preexposure vaccination should have their serum tested for neutralizing antibody 3 to 4 weeks after the last injection. Tests for rabies antibody can be arranged with or through state health department laboratories. If no antibody is detectable, booster doses should be given until a response is demonstrated. Persons with continuing exposure should receive 1.0 ml. boosters every 2 to 3 years.

When an immunized individual with previously demonstrated antibody is exposed to rabies, five daily doses of vaccine plus a booster dose 20 days later should be given to those having a severe exposure. A single booster is recommended if exposure is mild or questionable. If it is not known whether an exposed person had antibody, the complete postexposure antirabies treatment should be given.

2.3 Immunity

Immunity of those who received rabies immunization may be assessed by testing their serum serologically. The two recommended tests are the serum neutralization (SN) and indirect fluorescent rabies antibody (IFRA) procedures. The complement fixation (CF) test may also be used to detect rabies antibody, but it is not generally considered as sensitive as either of the other two.

2.4 Laboratory Problems

Although laboratory accidents are reasonably frequent, only one case of rabies developing in laboratory employees has been reported. The most frequent exposures in laboratories include cutting the fingers or hands when the animal head is opened and when pipetting and accidentally injecting the suspension of infected material. In such exposures, one or more booster injections are required.

Contraindications Precautions

Elective preexposure immunization should not be given to persons with histories of allergy to eggs or egg products. When rabies vaccine must be given to a person with a history of hypersensitivity to avian tissues, antihistaminic drugs should be used. Epinephrine is helpful in reactions of the anaphylactoid type.

When meningeal or neuromuscular reactions develop, vaccine treatment should be discontinued altogether. Corticotrophin or corticosteroids are used for such complications.

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RABIES EXPOSURE IN LABORATORIES—A STATEMENT ON SAFETY*

Two recent instances of exposure to rabies in laboratories point up the danger associated in working with fixed rabies virus. In one instance, a veterinary microbiologist in Texas died of rabies apparently contracted from a non-bite laboratory exposure sustained in the process of producing an animal rabies vaccine (MMWR, Vol. 21, No. 14). In the other instance, three persons in a state diagnostic laboratory were exposed when live virus being injected intracranially into a rabbit was sprayed into their eyes from a faulty syringe. In both laboratories, workers were handling a fixed laboratory strain of rabies virus — either the challenge virus standard (CVS) or the production virus (PV).

Because of these accidents, a committee* was appointed by the Director of the Center for Disease Control to review procedures used in laboratories where rabies virus is processed to make them as safe as possible. Some major points of consideration included virus strains, immunity, and kinds of procedures that entail special risk.

(1) Laboratory Strains of Virus, CVS and PV

The virus in CVS and PV, commonly referred to as "fixed virus," is extremely virulent for humans and animals; for example, 18 people died in Brazil after being vaccinated with vaccine containing live CVS virus that had not been adequately inactivated (1). Fixed virus in large doses injected intramuscularly will produce rabies in a large percentage of monkeys or dogs. Fixed rabies virus, therefore, should be treated with the same caution as wild rabies virus (also known as street virus).

(2) Pre-exposure rabies immunization

Any person who works directly with rabies virus, either in a rabies vaccine production laboratory or a rabies diagnostic laboratory, must be vaccinated against rabies and should have a serum neutralizing antibody titer of at least 1:5 before handling rabid animals or rabies virus. Should a titer of 1:5 or greater not develop following vaccination, at least two booster doses of vaccine should be given. The regimen for pre-exposure rabies vaccination and the recommendations for treatment, if exposed subsequently, are presented in the statement on Rabies Prophylaxis by the Public Health Service Advisory Committee on Immunization Practices (MMWR, Vol. 18, No. 43).

(3) Laboratory procedures that entail special risk

(a) Necropsy

Workers who perform necropsies on animals in the laboratory are at great risk, since they must use sharp instruments to open the cranium and remove the brain from infected animals. Special emphasis should be placed on protecting these people from direct

exposure; anyone performing a necropsy should take the following precautions:

1. Use a plastic face shield.
2. Wear gloves.
3. Hold the animal's head securely in a vise or other mechanical restraint while removing the brains.

(b) Trituration and specimen processing

Since rabies virus is liberated from the cells and is concentrated during the trituration and centrifugation of the brain and other infected tissues, persons pipetting or handling such suspensions must recognize the increased risks during those phases of their work. They should protect themselves and their colleagues by doing the following:

1. Use only pre-tested trituration and blending equipment known to be leak-proof. The equipment should be tested at least twice a year by filling it with dye in a solvent such as alcohol, wrapping it in a clean white cloth, and operating it. Leaks will be easy to identify.
2. Use safety pipettes and never mouth-pipet rabies virus.
3. Avoid spilling virus suspensions. If any suspension does get on the hands or other part of the body, it should be washed off with soap and water. If there is contamination through an abrasion, the accident should be reported to the supervisor, and a physician should be consulted and advised of the degree of exposure.
4. Use safe syringes, pre-tested to prevent leakage during animal inoculation.

Reference

1. Para M: An outbreak of post-vaccinal rabies in Fortaleza, Brazil, in 1960. Residual fixed virus as the etiological agent. *Bull Wld Hlth Org* 33:177-182. 1965

* The Committee members were Edward Seligman, Ph.D., Division of Biologics Standards, National Institutes of Health; A. L. Strating, D.V.M., Veterinary Biologics, U.S. Department of Agriculture; Robert H. Huffaker, D.V.M., Office of Center Director, and Keith Sikes, D.V.M., Veterinary Public Health Services, Epidemiology Program, CDC.

*From the May 27, 1972, issue of the *Morbidity and Mortality Weekly Report*, a publication of the Bureau of Epidemiology, CDC, Vol. 21, No. 21, p. 179 and 184.

ROCKY MOUNTAIN SPOTTED FEVER (RMSF) VACCINE

1. Description

- 1.1 Composition Rocky Mountain spotted fever vaccine is prepared from yolk sacs infected with *Rickettsia rickettsii*.
- 1.2 License Licensed.
- 1.3 Storage For optimal storage, refrigerate, but refrigeration is not essential.
- 1.4 Supplier Several, including Lederle Laboratories.
- 1.5 Reactions Mild, local reactions are fairly common. Severe, sometimes fatal, anaphylactoid reactions may occur in persons sensitive to eggs. Such individuals have histories of intolerance to eggs in food, so each prospective vaccinee should be questioned about this sensitivity.
- 1.6 Efficacy No field trials have been conducted. Field experience suggests vaccination ameliorates disease. See references. Experience in rickettsial laboratories is favorable.

2. Recommendations

- 2.1 General Recommended for persons who will be significantly exposed to *R. rickettsii* or to the ticks *Dermacentor variabilis* or *D. andersoni* and for those with heavy tick exposure.

The vaccine is specifically recommended for:

- (a) Persons who work directly with the disease agent in the laboratory.
- (b) Persons who work in the same laboratory or who come into the room while work is being done.
- (c) Caretakers of infected animals.

Persons who handle decontaminated media or glassware and laboratory and animal quarters maintenance personnel *need not be vaccinated*.

- 2.2 Dose Primary: three 1 ml. doses 7 to 10 days apart.

Booster: one 1 ml. dose after 1 year; repeat only for those with heaviest exposure.

- 2.3 Immunity There are no practical tests for immunity. All persons are considered susceptible unless they have been immunized or infected.

- 2.4 Laboratory Laboratory infections are frequent and, in the absence of specific treatment, such infections are usually fatal in the unvaccinated. Laboratory infections are acquired from inhalation of aerosol of highly infected materials such as yolk sacs, ticks, or tick feces. Skin contact with such materials has also produced infections. *R. rickettsii* from the usual media used in the laboratory does not survive drying, so danger of infection does not persist in a room more than half an hour after the aerosol is produced.

3. Contraindications

- Precautions Vaccine should not be given to persons who are sensitive to

eggs. Each prospective vaccinee should be queried regarding allergy or intolerance to eggs.

Bibliography

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2. Smadel, J. E. Rocky Mountain Spotted Fever Vaccine. *In* Symposium on the Spotted Fever Group of Rickettsiae. Medical Science Publication No. 7. Walter Reed Army Institute of Research, Washington, D.C., pp. 55-61, 1960.

RUBELLA VACCINE

1. Description

- 1.1 Composition The live attenuated rubella virus vaccine now available is prepared from either HPV-77 or Cendehill strain rubella virus in cell cultures of avian (duck embryo) or mammalian (canine kidney and rabbit kidney) tissues.
- 1.2 License Licensed.
- 1.3 Storage Keep refrigerated or frozen before reconstituting for use. After reconstitution, protect from exposure to bright light and use promptly.
- 1.4 Suppliers Merck, Sharp and Dohme (HPV-77-DE5, duck embryo vaccine); Parke, Davis and Co. (HPV-77-DK12, canine kidney vaccine); Phillips-Roxane, Inc. (HPV-77-DK12, canine kidney vaccine); and Smith, Kline & French (Cendehill, rabbit kidney vaccine).
- 1.5 Reactions Serious adverse reactions are very rare. Susceptible adult women have frequently reported lymphadenopathy, arthralgia, and transient arthritis beginning 2 to 4 weeks after vaccination; however, fever, rash, and other features of naturally acquired rubella have occurred uncommonly in association with vaccination. All vaccine-related symptomatology has been transient, and no specific treatment has been necessary.
- 1.6 Efficacy Efficacy has been documented in several well-controlled studies. See references.

2. Recommendations

- 2.1 General Recommended primarily for children between 1 year and puberty in order to eliminate the major source of rubella exposure to pregnant women. Pregnant women *should not be* given rubella vaccine. Routine immunization of adolescent and adult women of childbearing age should be discouraged to avoid inadvertently administering vaccine before pregnancy is evident. Females of childbearing age should be vaccinated only when the possibility of pregnancy is essentially nil.

Rubella is generally a mild illness, but when a woman in the early months of pregnancy acquires the illness, it poses a direct hazard to the fetus. Preventing this complication is the ultimate objective of immunization.

The vaccine is specifically recommended for:

- (a) Adults, particularly women, who are found susceptible to rubella by the HI antibody assay procedure and who work in a laboratory where natural "wild" rubella virus is being handled. Obviously, susceptible pregnant women should be excluded from such laboratory areas.
- (b) Other susceptible persons who enter laboratory or animal-care areas where work is under way with rubella virus. Any susceptible pregnant woman, however, should avoid contact with these areas.

Caretakers of infected animals should be screened serologically for susceptibility and vaccinated if necessary.

Personnel who handle decontaminated media and glassware and laboratory and animal quarters maintenance personnel (other than those described above) *need not be vaccinated*.

2.2 Dose

Primary: a single subcutaneous injection of vaccine in volume specified by the manufacturer.

Booster: possible need for periodic booster immunizations has not been determined. Present data indicates that immunity from a single dose of vaccine may be long lasting.

2.3 Immunity

Immunity following rubella infection appears to be long lasting, even after mild illness or clinically inapparent infections. Because of the mild nature and clinical variability of rubella, however, a history of rubella illness is usually not sufficiently reliable to insure an individual of natural immunity. Immunity to rubella can be assessed by quantitative serologic studies with the HI technique. Because of the variation among reagents and technical procedures, however, results of serological tests should be accepted only from laboratories of recognized competency that regularly perform these tests.

2.4 Laboratory

Problems

Laboratory accidents are extremely rare. Only one laboratory-acquired case has been reported. Although considerable concern has been expressed about exposure of susceptible women of childbearing age to rubella virus in the laboratory, laboratory-acquired rubella infections have rarely been observed or reported. That rubella virus is not highly infectious in the laboratory environment is supported by documented instances of susceptible laboratory workers failing to become infected even after accidental ingestion of virus material. It is not known, however, if pregnancy alters an individual's susceptibility to rubella infection; therefore, avoid exposing pregnant women to laboratory areas where rubella virus is being studied.

3. Contraindications

Precautions

Do not give pregnant women rubella vaccine.

Routine immunization of adolescent and adult women of childbearing age should be discouraged to avoid inadvertently administering vaccine before pregnancy is evident.

If there is reason to vaccinate a woman of childbearing age, do the following:

Determine rubella susceptibility by the HI procedure.

If she is susceptible (no detectable antibody), vaccinate her and advise strongly against pregnancy for the next 2 months. Preferably, she should be on a reliable birth control program.

Warn her of the frequent occurrence of self-limited arthralgia and possible arthritis beginning 2 to 4 weeks after vaccination.

Avoid giving rubella vaccine to persons in altered immune states such as might be present with leukemia, lymphoma, or

generalized malignancy or with steroid, alkylating drug, antimetabolite, or radiation therapy.

Be careful in administering vaccines to persons with known hypersensitivity to the species from which the vaccine cell system was derived (indicated on the vaccine package).

Bibliography

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4. Musser, S. J. Production of Rubella Virus Vaccine. Live Attenuated in Canine Renal Cell Cultures. *Amer J Dis Child* 188:355-361, August 1969.

RUSSIAN SPRING SUMMER ENCEPHALITIS (RSSE) VACCINE

1. Description

- | | |
|-----------------|--|
| 1.1 Composition | Russian Spring Summer Encephalitis (RSSE) vaccine is a crude formalin-inactivated, 10% mouse brain suspension. No stabilizer or preservatives have been added. |
| 1.2 License | Unlicensed. |
| 1.3 Storage | Store lyophilized vaccine at -20°C . After reconstitution with water for injection, use within a few hours and keep chilled at 4°C . until used. |
| 1.4 Supplier | Walter Reed Army Institute of Research, Washington, D.C. |
| 1.5 Reactions | Severe adverse reactions have occurred with this particular vaccine. A similarly prepared vaccine used in Russia has apparently been responsible for allergic demyelination encephalomyelitis and has produced infectious encephalitis from incomplete inactivation of the virus. |
| 1.6 Efficacy | The Soviet vaccine has been adequately documented for efficacy; however, the writer is unaware of any published reports on the efficacy of the Walter Reed vaccine. In our limited experience about 15% of persons receiving the initial series of vaccine developed demonstrable neutralizing antibody. |

2. Recommendations

2.1 General

Recommended for individuals who must handle virulent virus in other than maximum security facilities. The vaccine currently available from Walter Reed was produced more than a decade ago and, in view of its documented poor efficacy and adverse reactions, it should not be used unless it is *absolutely necessary*. The Soviets have a new, cell-culture-derived formalinized vaccine which has been reported to be safe and effective.^{1,1} If it could be obtained, it would undoubtedly be a safer and better vaccine to use.

The use of currently available vaccines may be avoided by conducting all work in equipment tested and found to be secure, so that the worker will not be exposed to the virus.

RSSE virus may be spread by aerosol, ingestion, or inoculation. Any person who may come in contact with the virus, because of lack of adequate facilities, should be vaccinated.

The vaccine is specifically recommended for the following—but *only* if the laboratory facilities are inadequate:

- (a) Persons working directly with the virus.
- (b) Other persons working in the same laboratory.
- (c) Animal caretakers.
- (d) Persons handling infected glassware or media.
- (e) Maintenance personnel.
- (f) Other persons entering the laboratory.

2.2 Dose Primary: subcutaneous inoculation of 1.0 ml. of vaccine in a series of four doses over a 6-month period.

Booster: annually.

2.3 Immunity

Immunity can be assessed by quantitative neutralization test in mice. A log neutralization index of ≥ 2.0 is considered evidence of protection.

2.4 Laboratory Problems

Laboratory infections with RSSE virus have been fairly common; at least 18 infections and two deaths have been reported.

3. Contraindications

Precautions

The vaccine should be given only to healthy adults who are not known to be sensitive to formalin or brain material. As a general rule, continued vaccination of individuals who have received 6 ml. of brain-derived vaccines is hazardous because of the risk of allergic encephalomyelitis.

1. General

1.1 Chumakov, M.P., et al. Apropos of the Rate of Antibody Accumulation in Patients during the Early Period After Vaccination and Revaccination against Tick Encephalitis. VOP Virus 9:601-604, September-October 1964.

1.2 Hammon, W. Mc.D. In Vaccines against Viral and Rickettsial Diseases of Man. First International Conference, PAHO. pp. 252-259, 1967.

2. Laboratory Accidents

Hanson, R.P., et al. Arbovirus Infections of Laboratory Workers. Science 158(3806):1283-1286, December 8, 1967.

SMALLPOX VACCINE

1. Description

1.1 Composition

Smallpox vaccine is prepared from vaccinia virus-infected calf lymph and is available both in glycerinated and lyophilized form. Various strains of vaccinia virus are currently used in vaccine production.

1.2 License

Licensed.

1.3 Storage

Store purified dried (lyophilized) calf lymph vaccine frozen; before reconstitution, however, it is quite stable at room temperature. The glycerinated vaccine requires constant refrigeration at all stages in its transport and storage at temperatures recommended by the manufacturer. Comparatively minor storage difficulties may reduce vaccine potency sufficiently to decrease efficacy in vaccination, particularly in revaccination.

1.4 Supplier

Dryvax (dried, calf lymph type) and Smallpox Vaccine, Liquid (calf lymph type), Wyeth Laboratories.

Mono-Vacc, Lincoln Laboratories.

1.5 Reactions

As with other medical procedures, smallpox vaccination is associated with a definite, measurable risk of morbidity and, rarely, death. A comprehensive national survey to ascertain the frequency of complications associated with vaccination in the United States during 1963 has been completed.¹ Among more than 6,000,000 primary vaccinees and nearly 8,000,000 revaccinees and their contacts, 12 cases of encephalitis following vaccination, nine cases of vaccinia necrosum, and 108 cases of eczema vaccinatum occurred. Seven persons died. A substantial number of less serious complications, some of which resulted in hospitalization, were also recorded. All deaths and virtually all complications occurred among those vaccinated for the first time. All adverse reactions to smallpox vaccination in CDC personnel should be reported immediately to members of the Smallpox Eradication Program medical staff who will assist in directing treatment.

1.6 Efficacy

The efficacy of smallpox vaccine has never been precisely measured in controlled trials. It is, however, generally agreed that vaccination with fully potent vaccine confers a high level of protection for at least 3 years and provides substantial but waning immunity for 10 years or more. Protection against a fatal outcome of the disease appears to extend over a longer period, perhaps for decades.

2. Recommendations

2.1 General

Smallpox, particularly variola major, remains a highly virulent disease even with excellent medical care. Recent outbreaks among unvaccinated persons in nonendemic areas following smallpox introductions have resulted in mortality rates of 40% and more. The success of smallpox vaccination is greatly dependent on the potency of the vaccine. Use of the more stable lyophilized vaccine would insure more consistently satisfactory results.

In the United States, routine vaccination of infants and revaccination of older children and adults represents the principal mechanism of defense against the indigenous spread of the disease once introduced. Persons who conceivably might be exposed in endemic or potentially endemic areas by virtue of international travel and persons likely to be exposed by infection newly introduced into the United States (that is, hospital personnel, other medical and public health personnel, and morticians) should be revaccinated every 3 years.

Specific recommendations for the vaccine follow:

- (a) All persons (technical staff, visitors, animal caretakers, and maintenance personnel) requiring entry into any laboratory area where variola virus is handled must be revaccinated yearly. Variola virus should be handled only in specific isolation laboratory areas. All glassware, media, or other materials from the smallpox isolation laboratories should be autoclaved or appropriately disinfected before being removed from the laboratory.
- (b) All other persons entering the building which contains the smallpox laboratory must be revaccinated at least every 2 years. This includes all secretaries, visitors, and maintenance and service personnel.
- (c) All other CDC employees should have valid primary vaccination and revaccination every 3 years.

2.2 Dose

Primary: vaccination or revaccination is achieved either by the multiple pressure method or by jet injection intradermally on the skin over the insertion of the deltoid muscle or on the posterior aspect of the arm over the triceps muscle. Primary vaccinations should be inspected at 8 to 10 days. Revaccinations of previously successfully vaccinated individuals should be inspected at 4 to 7 days. Absence of reaction at these time periods indicates an unsuccessful effort, *not* immunity. Repeat attempt should be made with a fresh lot of vaccine.

Booster: see above.

2.3 Immunity

A history of primary vaccination (with presence of vaccination scar) and/or revaccination within 3 years is satisfactory evidence of immunity. Serologic tests, specifically neutralization titers, are helpful in selected instances.

2.4 Laboratory

Problems

Laboratory-acquired infections with the poxviruses, including smallpox (variola), have been reported in unvaccinated or inadequately vaccinated persons. Such laboratory infections are exceedingly rare in adequately vaccinated persons (vaccination within 3 years). Accidental inoculation of variola virus into the eye or skin theoretically might result in a localized infection, but such has not been documented.

3. Contraindications

Eczema and other forms of chronic dermatitis in the individual to be vaccinated or in a household contact are contraindications to smallpox vaccination. If vaccination is required for an individual with dermatitis because of potential exposure in the laboratory or in an endemic area, Vaccinia Immune Globulin

(VIG) should be administered to the affected individual at the same time as the vaccine.

In pregnant women, vaccinia virus may, on occasion, cross the placental barrier during any stage of pregnancy and infect the fetus. Virtually all cases of fetal vaccinia have followed primary vaccination.

Patients with leukemia, lymphoma, and other generalized malignancies and individuals with altered immunologic competency (that is, persons on steroids, alkylating agents, antimetabolites, and radiation therapy) should not be vaccinated.

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1. Neff, J. M., et al. Complications of Smallpox Vaccination. I. National Survey in the United States, 1963. *New Eng J Med* 276:125-132, January 19, 1967.
2. WHO Technical Report Series No. 283, WHO Expert Committee on Smallpox, 1964.

1.4 Supplier

Immunobiological Activity, Biological Reagents Section, Laboratory Division, CDC

1.5 Reactions

The vaccination site should be inspected 7 to 10 days after vaccination. The presence of a vesicle or coalescing vesicular, pustular, or crusted papules on an erythematous indurated base is indicative of a good "take." Approximately 5% of recipients may have mild systemic symptoms, consisting of malaise, headache, myalgia, and arthralgia, 5 to 7 days after vaccination. Axillary node tenderness may be noted. These symptoms generally subside within 72 hours and may be alleviated by analgesics. No closing sores following use of the vaccine. The vaccine has been safely administered to over 2,000 individuals.

1.6 Efficacy

Figsbach¹ and Hornick reported the most recent study of vaccine efficacy. Given in doses of 10^6 - 10^8 organisms by the aerosol route, the vaccine provided 100% protection to volunteers challenged with 2,500 times the minimum infective respiratory dose of a virulent strain in man. Protection against intradermal inoculation of a virulent strain was also excellent. The safety and efficacy of the vaccine has also been described by Sadaw and McCrumb.²

2. Recommendations

2.1 General

Should be considered for all persons whose vocations or field work bring them into frequent and regular contact with wild rodents in infested areas. All laboratory workers who are likely to have even casual exposure to areas where *Francisella tularensis* is under study should be immunized, because laboratory workers are frequently infected.

The vaccine is specifically recommended for:

- (a) Persons working in laboratories where *F. tularensis* or potentially infected material is being investigated.

TETANUS TOXOID

Information on tetanus toxoid is given under "Diphtheria and Tetanus Toxoids."

TULAREMIA VACCINE

1. Description

1.1 Composition

Tularemia vaccine, live, attenuated, is made with a lyophilized, viable, attenuated variant of *Pasteurella tularensis*. The vaccine is prepared from a broth culture of the organism grown in modified casein partial hydrolysate medium. A sucrose gelatin stabilizer is added to the harvest of the culture, and the vaccine is lyophilized for distribution. No other additives or preservatives are added to the vaccine. When the vaccine is reconstituted, each vial contains 2 ml. with approximately 10^9 organisms per ml. The amount in each vial should be sufficient for vaccinating 50 to 100 people. Diluent and sterile needles suitable for scarifying are provided with each vial.

1.2 License

New drug; limited to investigational use.

1.3 Storage

Store at freezer temperatures (-10° to $-20^{\circ}\text{C}.$); if kept under refrigeration, vaccine may be used for 8 hours after reconstitution. *Eight hours after reconstitution, any remaining vaccine must be autoclaved and discarded.* Do not use after expiration date.

1.4 Supplier

Immunobiologics Activity, Biological Reagents Section, Laboratory Division, CDC.

1.5 Reactions

The vaccination site should be inspected 7 to 10 days after vaccination. The presence of isolated or coalescing vesicular, pustular, or crusted papules on an erythematous indurated base is indicative of a good "take." Approximately 5% of recipients may have mild systemic symptoms, consisting of malaise, headache, myalgia, and arthralgia, 5 to 7 days after vaccination. Axillary node tenderness may be noted. These symptoms generally subside within 72 hours and may be alleviated by analgesics. No cicatrix forms following use of the vaccine. The vaccine has been safely administered to over 2,000 individuals.

1.6 Efficacy

Eigelsbach¹ and Hornick reported the most recent study of vaccine efficacy. Given in doses of 10^6 - 10^8 organisms by the aerosol route, the vaccine conveyed 100% protection to volunteers challenged with 2,500 times the minimum infective respiratory dose of a virulent strain in man. Protection against intradermal inoculation of a virulent strain was also excellent. The safety and efficacy of the vaccine has also been described by Saslaw and McCrumb.²

2. Recommendations

2.1 General

Should be considered for all persons whose vocations or field work brings them into frequent and regular contact with wild rodents in tularemia enzootic areas. All laboratory workers who are likely to have even casual exposure to areas where *Francisella tularensis* is under study should be immunized, because laboratory workers are frequently infected.

The vaccine is specifically recommended for:

- (a) Persons working in laboratories where *F. tularensis* or potentially infected material is being investigated.

- (b) Caretakers of animals infected or potentially infected with *F. tularensis*. This group includes laboratory and animal quarters maintenance personnel.

These groups need not be vaccinated:

- (a) Visitors, secretaries, and other such persons—all of whom should be barred from the specific laboratory area (hood room) where work with *F. tularensis* is under way.
- (b) Personnel employed in disposing of decontaminated items, such as glassware, old culture materials, and equipment.

2.2 Dose

Primary: one drop of the reconstituted vaccine applied to scarification.

Booster: duration of protection is unknown; no routine schedule of booster doses has been devised.

2.3 Immunity

Susceptibility or prior exposure to tularemia can be imperfectly assessed by a skin test, antibody titers, and the histories of natural infection and immunization.

2.4 Laboratory Problems

VanMetre and Kadull³ stated that practically every nonvaccinated individual who consistently works with the organism becomes infected, usually by inhalation.

Most laboratory infections result from exposure to uncovered or spilled cultures; 129 have been reported. In some instances, disease has developed in persons who simply entered the laboratory area. Minor skin injuries from objects contaminated with *F. tularensis* have resulted in the ulcero-glandular form. Serologic studies have demonstrated a number of asymptomatic cases among persons who have either worked with the organism or have simply entered laboratories where the organism was being studied.

3. Contraindications

Precautions

The vaccine must be administered by or under the supervision of the physician who requested the vaccine and completed Form FD-1573, "Statement of Investigator."

The vaccine should be administered only to healthy men and women from 18 to 65 years old, since investigations have been conducted exclusively in this population. The effects of administering the vaccine during pregnancy have not been studied, and the vaccine is not recommended for pregnant women.

Patients with eczema or chronic dermatosis should not be vaccinated. Exercise caution in vaccinating persons with normal skin who have direct and frequent contact with eczematous individuals.

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1. Eigelsbach, et al. Live Tularemia Vaccine. I. Host-Parasite Relationship in Monkeys Vaccinated Intracutaneously or Aerogenically. *J Bact* 84(5):1020-1027, November 1962.

2. Saslaw, S., et al. Tularemia Vaccine Study. I. Intracutaneous Challenge; and II. Respiratory Challenge. Arch Int Med 107(5):689-701 and 702-714, May 1961.
3. VanMetre, T. E., Jr., and Kadull, P. J., Laboratory Acquired Tularemia in Vaccinated Individuals: A Report of 62 Cases. Ann Int Med 50(3):621-663, March 1959.

TYPHOID VACCINE

1. Description

- 1.1 Composition Typhoid vaccine is a heat-killed, phenol-preserved suspension of *S. typhi* organisms containing 1,000 million cells and not more than 0.035 mg. per ml. of total nitrogen in phosphate-buffered isotonic saline. At the present time, strain No. 58 (Panama strain) serves as the standard.
- 1.2 License Licensed.
- 1.3 Storage Refrigerate at 2° to 8°C.
- 1.4 Supplier Eli Lilly and Co., Wyeth Laboratories, and other drug companies.
- 1.5 Reactions Local reactions of swelling, inflammation, and pain are common. Systemic reactions of malaise, fever, headache, and nausea are relatively common. Serious systemic reactions, especially postvaccinal neurologic disorders, are extremely rare. Reimmunization can cause reactions that are more severe than those due to the primary series.
- 1.6 Efficacy Intradermal administration of vaccine practically eliminates the possibility of systemic reactions without sacrificing protective antibody levels. The intradermal route should not be used, however, for the primary course.
- Heat-killed, phenol-preserved typhoid vaccine stimulates protective antibody levels in 60 to 90% of recipients, depending upon prior antibody level. The acetone-dried vaccine has been reported to afford protective levels of greater than 90%. Respective vaccine efficacy has been documented in several well-controlled field trials. Results of these trials have made it clear that the acetone-killed typhoid vaccine should be strongly considered as the vaccine to replace the one currently in use. See references.

2. Recommendations

- 2.1 General Recommended for individuals who may be exposed to *S. typhi* in any manner permitting oral intake and for travelers to areas where typhoid fever is known to be endemic or hyperendemic. The vaccine is specifically recommended for:
- (a) Persons who work directly with *S. typhi*.
 - (b) Caretakers of infected animals.
- These groups *need not be* vaccinated:
- (a) Persons who work in the same laboratory though not with *S. typhi*.
 - (b) Personnel who handle media and glassware.
 - (c) Laboratory and animal maintenance personnel.
 - (d) Other personnel who may enter laboratory and animal care areas where *S. typhi* is being used.
- 2.2 Dose Primary for adults: 0.5 ml. subcutaneously on two occasions separated by 4 or more weeks.
- Booster: 0.5 ml. subcutaneously or 0.1 ml. intradermally every

3 years. Even if more than 3 years have elapsed, only 0.5 ml. subcutaneously or 0.1 ml. intracutaneously should be used.

2.3 Immunity

Antibody levels against O, H, and Vi antigens can be assessed. Unless definite changes of level are measured, however, they are not diagnostic. Neither do high antibody levels guarantee immunity; anti-O and anti-Vi levels are especially unreliable.

2.4 Laboratory Problems

Although 292 cases of laboratory-acquired typhoid fever have been reported, most of these were acquired in Europe during 1915-1948. In recent years in the United States infections have been rare. The most recent account of laboratory-acquired infection implicated a lactose-fermenting strain of *S. typhi* from a glassware washer.² Considering the number of people directly and possibly indirectly involved with various aspects of *S. typhi* over the decades, this is truly a remarkable record. The real hazard among laboratory workers is generally conceded to be carelessness, such as that contributing to the accidental aspiration of a broth culture.

3. Contraindications:

Precautions

Contraindications include the presence of any acute illness or exposure to an infectious agent which may produce illness. Neither should typhoid vaccine be given to patients with severe debilitating chronic disease or chronic diseases that require continuous and concomitant administration of cortico-steroids.

Bibliography

1. Vaccine Efficacy

- 1.1 Ashcroft, M. T., et al. A Seven-Year Field Trial of Two Typhoid Vaccines in Guyana. *Lancet II*:1056-1059, November 18, 1967.
- 1.2 Ashcroft, M. T., Ritchie, J. M., and Nicholson, C. C. Controlled Field Trial in British Guiana School Children of Heat-Killed-Phenolized and Acetone-Killed Lyophilized Typhoid Vaccines. *Amer J Hyg* 79(2):196-208, March 1964.
- 1.3 Yugoslav Typhoid Commission. A Controlled Field Trial of the Effectiveness of Phenol and Alcohol Typhoid Vaccines: Final Report. *Bull WHO* 26(3):357-369, 1962.

2. Laboratory Accidents

- Kunz, L. J., and Ewing, W. H. Laboratory Infection with a Lactose-Fermenting Strain of *Salmonella typhi*. *J Bact* 89(6):1629, June 1965.

TYPHUS FEVER (EPIDEMIC) VACCINE

1. Description

- 1.1 Composition Typhus fever (epidemic) vaccine is prepared from yolk sacs infected with *Rickettsia prowazeki*.
- 1.2 License Licensed.
- 1.3 Storage For optimal storage, refrigerate, but refrigeration is not essential.
- 1.4 Supplier Several, including Eli Lilly and Co., Lederle Laboratories, and Merck, Sharp, and Dohme.
- 1.5 Reactions Mild, local reactions are fairly common. Severe, sometimes fatal anaphylactoid reactions may occur in persons sensitive to eggs. Such individuals have histories of intolerance to eggs in food, so each prospective vaccinee should be questioned about this sensitivity.
- 1.6 Efficacy No direct field trials have been carried out, but field experience has been favorable. Experience in rickettsial laboratories is also favorable. (See references.)

2. Recommendations

- 2.1 General Recommended for persons who will be exposed to *R. prowazeki* or to human lice and for travelers to areas where louse infestation is common; such areas are now, in general, the mountainous tropics.

The vaccine is specifically recommended for:

- (a) Persons who work directly with the disease agent in the laboratory.
- (b) Persons who work in the same laboratory or who come into the room while work is being done.
- (c) Caretakers of infected animals.
- (d) Persons who enter laboratory or animal care areas while laboratory work is being done.

- 2.2 Dose Primary: two 0.5 ml. (or 1.0 ml., see package insert) doses 1 to 4 weeks apart.

Booster: dose as recommended by manufacturer. A single injection of vaccine at intervals of 6 to 12 months for as long as opportunity for exposure exists. The primary series need never be repeated for booster doses to be effective.

- 2.3 Immunity Immunity is best assessed by the neutralization test (of toxic substance), but the test is difficult to perform. All persons are considered susceptible unless they have been immunized or infected.

- 2.4 Laboratory Problems

Eighty-two laboratory infections have occurred. In the absence of specific treatment, such infections were usually fatal in the unvaccinated. Laboratory infections are acquired from inhaling aerosol of highly infected materials such as yolk sacs, lice, or louse feces. *R. prowazeki* from the usual media used in the laboratory does not survive drying; consequently, danger

of infection does not persist in a room for more than a half hour after the aerosol is produced.

3. Contraindications

Precautions

Do not give the vaccine to persons who are sensitive to eggs. Each person to be vaccinated should be asked if he can safely eat eggs.

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VENEZUELAN EQUINE ENCEPHALITIS (VEE) VACCINE

1. Description

- 1.1 Composition** Venezuelan equine encephalitis (VEE) virus vaccine is a live virus preparation limited to the immunization of persons at risk to infection with virulent strains of VEE virus. The vaccine is propagated in primary fetal guinea pig heart tissue cultures maintained in Hank's balanced salt solution, supplemented with 0.5% Human Serum Albumin (USP), and without antibiotics.
- 1.2 License** Unlicensed.
- 1.3 Storage** Store lyophilized vaccine at -20°C .
- 1.4 Supplier** Immunobiologics Activity, Biological Reagents Section, Laboratory Division, CDC.
- 1.5 Reactions** A small but variable percentage of persons administered this vaccine experience adverse reactions of mild to moderate severity. Reactions have been characterized by transient malaise, myalgia, and headache, with or without fever of 12 to 24 hours' duration, occurring 1 to 3 days after inoculation. Less frequently, biphasic or late reactions, for example, between 5 and 10 days after inoculation, have occurred. In such instances, symptomatology has been an extension of that described above. Adverse reactions are treated symptomatically. See references.
- 1.6 Efficacy** Efficacy has been documented. See references.

2. Recommendations

- 2.1 General** Recommended only for personnel who are at high risk because of their laboratory or field studies. The vaccine should be administered to individuals who may be exposed to virulent, exotic strains of VEE virus. The vaccine is not recommended for those handling domestic strains, since natural illness with such strains may be less severe than vaccine reactions.
- The vaccine is specifically recommended for:
- (a) Persons who work directly with the disease agent in the laboratory.
 - (b) Persons who work in the same laboratory though not with the specific organism.
 - (c) Caretakers of infected animals.
 - (d) Personnel who handle contaminated media and glassware before autoclaving.
 - (e) Laboratory and animal quarter maintenance personnel.
 - (f) Other persons who enter laboratory or animal-care areas where work with the organism is under way.

- 2.2 Dose** Primary: a single 0.5 ml. dose of properly reconstituted vaccine subcutaneously.

Booster: routine boosters are not recommended. However, persons who do not develop an HI titer of 1:40 or greater within 4 weeks after the primary inoculation should receive a

second inoculation. If the HI titer following this second viable VEE vaccination does not reach 1:40 or greater, a serum neutralization assay should be done; a log virus neutralization index of 1.7 or greater is considered indicative of adequate protection.

Revaccination: Vaccinated persons at risk should be screened periodically for HI titer. If the HI titer has declined to 1:20 or less, revaccination is recommended.

2.3 Immunity

Immunity can be assessed by quantitative serologic methods. The most indicative is the virus neutralization test performed either in mice or in appropriate cell systems.

2.4 Laboratory Problems

Laboratory infections with VEE virus are very common. One hundred and eighteen cases and one death have been recorded. (See references.) VEE produces more laboratory infections than any other arbovirus reported. As many as 24 cases have been reported as resulting from a single laboratory accident. The virus is infectious by aerosol as well as by inoculation. Infected animals excrete the virus, and animal caretakers have been infected while handling animal litter.

3. Contraindications Precautions

The teratogenic properties of the vaccine for the human fetus have not been characterized. Therefore, the vaccine is not recommended for pregnant females.

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2. Laboratory Accidents

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YELLOW FEVER (YF) VACCINE

1. Description

1.1 Composition Yellow fever (YF) vaccine is a live, clarified aqueous-base extract of living chick embryos infected with 17D YF virus. No preservative or protein stabilizer is added.

1.2 License Licensed.

1.3 Storage Store in the unopened glass ampule in the freezing compartment of a refrigerator (at approximately -20°C). At this temperature, the vaccine retains its potency for at least 12 months. The vaccine must be reconstituted with sterile sodium chloride injection, USP, (contains no preservative) immediately before use. Reconstituted virus must be kept cool and used within 60 minutes.

1.4 Supplier The National Drug Co.

1.5 Reactions Mild systemic reactions characterized by fever and malaise occur in less than 10% of vaccinated individuals and are rarely severe enough to require medical attention. When the vaccine is given together with smallpox vaccine by the jet injector technique, a typical vaccinal reaction occurs at the site of injection. More severe generalized hypersensitivity reactions may occur in egg-sensitive individuals. See below. Encephalitis has been reported rarely in infants under 1 year of age. A single fatality from encephalitis in a 3-year-old girl vaccinated with 17D virus is on record; virus was isolated from the child's brain.

1.6 Efficacy Vaccine efficacy, measured by serologic response, approaches 95%. Several large studies have documented yellow fever vaccine efficacy.

2. Recommendations

2.1 General Recommended for individuals who may be exposed to virulent yellow fever virus under natural or laboratory conditions and for persons traveling to countries requiring an International Certificate of Vaccination against yellow fever and to other areas in which yellow fever is known or suspected to occur.

Laboratory workers and caretakers who may have intimate or chance exposure to yellow fever virus should be vaccinated.

The vaccine is specifically recommended for:

- (a) Persons working directly with virulent strains of YF virus and persons working directly with 17D virus who may be exposed to high mouse passage virus that has reverted to virulence.
- (b) Persons who work in the same laboratory although not with YF virus.
- (c) Caretakers of animals infected with YF virus.
- (d) Persons handling infected glassware.
- (e) Maintenance personnel.
- (f) Other persons entering laboratories where work with the virus is under way.

2.2 Dose

Primary: single subcutaneous injection of 0.5 ml.

Revaccination: required after a lapse of 10 years. More frequent vaccinations at 5-year intervals are advisable for persons working with virulent virus in the laboratory.

2.3 Immunity

Immunity can be assessed by quantitative serologic tests. Only the serum neutralization test adequately reflects immunization with 17D virus. Hemagglutination-inhibiting antibody may not develop in some individuals, and, in most, it is of low titer. Complement fixing antibody rarely develops. Neutralizing antibody lasts at least 16 years after immunization. No skin test is available. History of natural disease, if based only on clinical information, is not reliable because YF infection may mimic a number of other viral diseases, including hepatitis and influenza.

2.4 Laboratory Problems

Thirty-eight laboratory infections with yellow fever virus have occurred. Rarely have these been associated with bites of infective mosquitoes. Most have resulted from contact with or inhalation of infectious material (for example, blood, serum, and mouse brain tissue). Widespread immunization of laboratory personnel has eliminated the danger of infection. Hospital personnel have been infected through contact with the blood of infected patients.

3. Contraindications Precautions

Relative contraindications to the use of 17D vaccine include: history of egg sensitivity; pregnancy; age under 1 year; and concomitant administration of immunosuppressive drugs, corticosteroids, or X-ray therapy.

There are no absolute contraindications to the use of the vaccine. Pregnant women and infants in the high risk areas may require vaccination after the relative risks have been considered. Similar considerations may apply to persons receiving immunosuppressive or steroid therapy. Egg-sensitive or chicken-sensitive individuals should receive an intradermal test with 0.02 ml. of vaccine. A positive test (urticarial wheal) may contraindicate administration of the vaccine. In cases with minimal skin test reactions or with a negative test but a strongly suggestive allergic history, immunization may be attempted by scarification. Two scratches about 1 centimeter long are made and a drop of vaccine is rubbed into each. Epinephrine should be available for use during skin testing and/or scarification.

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VACCINATION DURING PREGNANCY

	TETANUS-DIPHTHERIA	POLIOMYELITIS	MUMPS	MEASLES	RUBELLA	INFLUENZA	TYPHOID	SMALLPOX	YELLOW FEVER	CHOLERA	PLAGUE	RABIES	HEPATITIS-A (Infectious)	VARICELLA ZOSTER
RISK FROM DISEASE TO PREGNANT FEMALE	Severe morbidity. Tetanus mortality 60%, diphtheria mortality 10% unaltered by pregnancy.	No increased incidence in pregnancy, but possible increased risk of more severe disease.	Low morbidity and mortality, not altered by pregnancy.	Significant morbidity, low mortality, not altered by pregnancy.	Low morbidity and mortality, not altered by pregnancy.	Possible increase in morbidity and mortality during epidemic of new antigenic strain.	Significant morbidity and mortality, not altered by pregnancy.	Mortality increased to 90% during pregnancy (variola major).	Significant morbidity and mortality, not altered by pregnancy.	Significant morbidity and mortality, not altered by pregnancy.	Significant morbidity and mortality, not altered by pregnancy.	Near 100% fatality not altered by pregnancy.	Significant morbidity, low mortality, not altered by pregnancy.	Low morbidity and mortality, not altered by pregnancy.
RISK FROM DISEASE TO FETUS OR NEONATE	Neonatal tetanus mortality 60%.	Anoxic fetal damage reported. 50% mortality in neonatal disease.	Questionable association with fibroelastosis in neonate.	Significant increase in abortion rate. No malformations reported.	High rate of abortion and congenital rubella syndrome in first trimester.	Possible increased abortion rate. No malformations confirmed.	Unknown.	Possible increased abortion rate. Congenital smallpox reported.	Unknown.	Unknown.	Unknown.	Determined by maternal disease.	Transmission to fetus and possibility of neonatal hepatitis.	Possible increased risk of severe disease in neonate, especially if premature.
VACCINE	Combined tetanus: diphtheria toxoids preferred; request adult DT from pharmacist.	Live, attenuated virus (Sabin) vaccine.	Live, attenuated virus vaccine.	Live, attenuated virus vaccine.	Live, attenuated virus vaccine.	Inactivated type A and type B virus vaccines.	Killed bacterial vaccine.	Live vaccinia virus vaccine.	Live, attenuated virus vaccine.	Killed bacterial vaccine.	Killed bacterial vaccine.	Killed virus vaccine (Duck embryo). Rabies immune globulin.	Pooled immune serum globulin.	Zoster immune globulin or convalescent zoster plasma.
RISK FROM VACCINE TO FETUS	None confirmed.	None confirmed.	None confirmed.	None confirmed.	None confirmed.	None confirmed.	None confirmed.	Rare cases of congenital vaccinia.	Unknown.	Unknown.	None reported.	Unknown.	None reported.	None reported.
INDICATIONS FOR VACCINATION DURING PREGNANCY	Lack of primary series, or no booster within past 10 years.	Not recommended routinely for adults in USA. In epidemics, mandatory to immunize all adults.	Contraindicated.	Contraindicated.	Contraindicated.	Recommended only for patients with serious underlying diseases.	Not recommended routinely except for close, continued exposure or travel to endemic areas.	Not recommended routinely in U.S.A. except for at risk populations (hospital and public health workers). Avoid in pregnancy except in cases of probable exposure.	Contraindicated except for unavoidable exposure.	Only to meet international travel requirements.	Very selective vaccination of exposed persons.	Pregnancy does not alter indications for prophylaxis. Each case must be considered individually.	Household or institutional exposure. Travel in developing countries.	Experimental drug. No PHS recommendation for use in pregnancy.
DOSE/SCHEDULE	Primary: 3 doses at 1-2 month intervals. Booster: 0.5 cc per 10 years.	Monovalent or trivalent OPV. Primary series of 3 doses at 1-2 month intervals, or booster dose.	————	————	————	Primary: 2 doses 6-8 weeks apart in early fall. Booster: Single dose.	Primary immunization 2 injections 4 weeks apart. Booster injection every 3 years as indicated.	Give VIG (0.3cc/kg) with primary vaccination, when available. Revaccination without VIG.	Single injection per 10 years.	2 injections 4-8 weeks apart.	Consult public health authorities for indications and dosage.	Consult public health authorities for indications and dosage.	2.0 cc IM for adults for exposure or short-term foreign travel.	————
COMMENTS	Updating of immune status should be part of antepartum care.	Vaccine indicated for susceptible women traveling in endemic areas.	————	2.0 cc Immune Serum Globulin to exposed, susceptible female.	Teratogenicity of vaccine virus suspected but not confirmed.*	Vaccination of pregnant women before new virus strain left to discretion of physician.	————	**	Postponing travel preferable to vaccination.	Vaccine of low efficacy.	————	————	Not recommended for protection against hepatitis-B (serum).	CDC is maintaining surveillance of varicella during pregnancy.

*To determine the teratogenicity of rubella virus and rubella vaccine virus, the Center for Disease Control maintains a registry of *Congenital Rubella Syndrome* and of *Rubella Vaccination During Pregnancy*. This surveillance allows continuing evaluation of the rubella vaccination program. Therefore, all cases concerning either one of these problems should be reported to the CDC.

**Though congenital vaccinia and abortion following smallpox vaccination are not unknown, they are certainly rare events. The safest procedure for primary smallpox vaccination during pregnancy is to administer a simultaneous, separate injection of vaccinia immune globulin (VIG). But when VIG is not available and vaccination is mandatory, during epidemics or travel in endemic areas, vaccine should not be withheld. The risk of maternal and fetal death from smallpox under such conditions far outweighs the risks from vaccination itself. Complications following smallpox revaccination are very rare, and VIG is not indicated.

Inquiries for additional information or assistance can be directed to:

Center for Disease Control
Immunization Branch
State and Community Services Division
Atlanta, Georgia 30333
Telephone: 404/633-3311 Extension 3736

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